

Glyphosate - Comments and data received during Public Consultation

RAC-39

Summary

- A total of 293 comments
- Comments received from 8 MS (FI, ES, NO, DK, BE, NL, SE, FR), other comments were from organisations or individuals.
- 40% of the comments received were variations of standardised text
- 30% of the comments addressed other issues, (i.e. risk assessment) and did not provide any new data relevant for classification
- 20% contained detailed and scientifically justified arguments
- 1% discussed antibacterial activity of glyphosate
- 2% discusses issues related to ecotoxicology
- The remaining comments are related to general concerns, not provided in standardised text

Standardised comment from individuals

- *“I am extremely concerned about the flawed evaluation of carcinogenicity data pointed out by top scientists in an open letter.”*
- *“I urge you to include all independent studies used in the IARC monograph in your assessment.”*
- *“Also please review the studies submitted by industry with extreme caution because of their potential conflict of interest, and make sure they become publicly available for scrutiny by other scientists.”*
- *“Ensure you take into account studies from mice that show that glyphosate is carcinogenic and the six studies from registers of human cancer cases, when you decide how to classify glyphosate.”*

Standard reply from the DS

- *The hazard assessment and toxicological evaluation of carcinogenicity data by the dossier submitter has been performed independently according to the ECHA guidance documents and was not based on the former risk assessment for the approval of glyphosate or evaluations by other institutions. However, all relevant critical discussions of the past are considered in the assessment by ECHA.*
- *All studies evaluated in the IARC monograph on glyphosate were discussed in the BfR addendum from August 2015, which was submitted together with the IARC monograph as addendum to the CLH dossier. There is agreement that all studies used in the IARC monograph on glyphosate will be considered in the final discussion of the CLH dossier.*
- *All available studies including all studies submitted by industry as well as those published in the scientific literature are assessed very carefully in compliance with common scientific principles.*
- *According to EU directives and national laws of EU member states the notifiers of pesticides are legally obligated to submit a range of studies which have to be performed in compliance with guidance documents. The quality of studies submitted by industry and of published studies of other origin is assessed by common criteria.*
- *If the studies provided by industry could or should become publically available in full, is a legal but not a scientific question. The decision on that is not up to the competent authorities of the DS nor up to ECHA's RAC. At least, these studies are published by EFSA in great length in Volume 3 of the RAR.*
- *All available studies in mice and also all studies in other animal species and in humans are taken into account for the decision on classification of glyphosate.*
- *In support of our answer to this comment on the carcinogenicity of glyphosate, we are providing an additional assessment according to the IPCS 'Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis' as an Addendum to the CLH dossier, which is attached at the end of this document.*

Comments related to specific hazard classes

- Acute toxicity, one comment
- STOT SE; no comments
- Skin irritation; no comments
- Eye irritation; four comments. 3 supporting Eye Dam. 1, H318, one commenting on classification of the formulation
- Resp. Sens; two comments, one supporting no classification and the other is not considered to have any impact on the classification discussion
- Skin Sens; no comments

Comments related to specific hazard classes

- **STOT RE:**

- 6 comments supporting STOT RE 2 (4 MS, 2 organisation)
- 2 comments in favour of no classification (organisation)
- 1 comment from organisation not relevant for classification (referring to non-standard tests)

Comments related to specific hazard classes

- **Reproductive toxicity:**

- 1 comment from an organisation supported no classification
- 1 MS supported no classification for reproductive toxicity, but noted that a conclusion on effects on or via lactation is missing in the CLH proposal.
- 2 MS and 1 individual considered that a classification could be relevant for developmental toxicity.
- 1 comment from an individual referred to a publication describing concern for birth defects.
- 1 comment from an organisation supported at least Repr. 2; H361.
- 1 comment from an individual supported Repr. 1B.
- 1 comment from an organisation on male reproductive organs, supporting Repr. 1B.
- 1 comment from an organisation indicated concerns for ED effects and low dose effects on reproduction.
- 2 organisations and one individual commented on the epidemiological studies and associations between GBH and miscarriage and ADHD.
- 1 comment from an organisation commented on the low-dose effects and absence of a dose-response relationship.

Comments related to specific hazard classes

- **Mutagenicity**

- 3 organisations; strong evidence of genotoxic properties of glyphosate as a mechanism for carcinogenicity.
- 6 individuals and 1 organisation supported a classification (no category specified)
- 1 MS and 1 organisation supported Muta 2
- 2 MS and 1 organisation; supported no classification
- 1 MS and 1 individual considered that further testing is necessary in order to draw any conclusions

Comments related to specific hazard classes

- **Carcinogenicity**

- 1 organisation on behalf of 2 million members support Carc. 1B
- 7 organisations and 8 individuals supported Carc. 1B
- 1 organisation and 14 individuals supported classification for carcinogenicity without specifying a category
- 1MS supported a classification as Carc. 2
- 1 MS, 1 national authority and 1 organisation supported possibly Carc. 2
- 2 MS and 1 individual and 1 organisation supported no classification
- 1 MS described inconsistencies between the CLH report and the RAR
- 1 MS commented on the statistical methods used analysing the animal data

Thank you for your attention!