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Comments from the Umweltinstitut München e.V. on the public consultation on the Assessment Report on the active substance Glyphosate to EFSA

Genotoxicity

Vol. 3, B.6.4. GENOTOXICITY, p. 5 ff

The experts on genotoxicity (DNA damage) at the Institute for Cancer Research at the Medical University of Vienna Prof. Dr. Siegfried Knasmüller and Dr. Armen Nersesyan examined 53 studies of glyphosate DNA damage that were submitted by manufacturers as part of the previous approval process. Based on these studies, the European Food Safety Authority (EFSA) came to the conclusion that glyphosate is not genotoxic and with this classification contradicted the Cancer Research Agency of the World Health Organization (IARC), which classified glyphosate as genotoxic. In reviewing these studies, the professors also came to a different conclusion. Only 2 of the 53 studies that were used for the current EU approval of glyphosate can be classified as "reliable" according to their analysis. The majority (34 of 53 studies) rated them as "not reliable" and the remaining 17 as only "partially reliable". It should not be repeated that studies have classified glyphosate as Non-DNA Damaging. The report of the Viennese experts must absolutely be taken into account and the studies submitted by the industry should be critically examined when in the last detail. Inadequate studies should not be accepted as reliable.

Source:

<https://www.global2000.at/sites/global/files/Analyse-Glyphosat-Studien.pdf>

Long-term toxicity and carcinogenicity

Vol. 3, B.6.5. LONG-TERM TOXICITY AND CARCINOGENESIS, p. 5 ff

The International Agency for Research on Cancer (IARC) of the World Health Organization (WHO), tested the active ingredient glyphosate based on what was available to it (only publicly available studies) in 2015 and came to the conclusion that

- Glyphosate is "probably carcinogenic in humans" (carcinogen group 2A)
- there is sufficient evidence available that glyphosate is carcinogenic in laboratory animals
Furthermore, the IARC found a positive relationship between glyphosate and the occurrence of non-Hodgkin lymphoma (malignant lymph gland cancer that occurs in all Organs of the human body).

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Source:

IARC: Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. Lancet Oncology, March 20, 2015, <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf>

Fate and behaviour in air

Vol. 1, 2.8.3 Summary of fate and behaviour in air, p. 567

The results of the German study “Pesticide pollution of the air” prove that glyphosate is transported through air for miles. The analysis was initially published in 2020 and has now been peer-reviewed by independent scientists and published in the journal "Environmental Sciences Europe". Glyphosate was detected at every single one of the total 69 measuring points distributed throughout Germany in both passive air samplers and filter mats. It was found far away from potential fields of origin, even in national parks like the Bavarian Forest or on the Harzer Brocken. Concentrations peaked at 3176.8 ng/sample (median: 98.4 ng/ sample). In Vol. 1 of the RAR is recored: „Based on glyphosate properties, the active substance is not considered volatile and has no potential for long range transport according to FOCUS guidance Air (2008). However, it should be noted that glyphosate is quantified in a national exploratory pesticide campaign in air in France.“ The fact that glyphosate spreads through the air must not only be noted in the approval process. These findings show that the previous assumptions were wrong and under these conditions a reapproval of glyphosate cannot be an option.

The comparable monitorings cited in the study mentioned should also be taken into account.

Source:

<https://enveurope.springeropen.com/articles/10.1186/s12302-021-00553-4>

Birds and other terrestrial vertebrates

Vol 1 2.9.1.1 Acute toxicity to birds p. 577 ff,

Vol 1 2.9.1.2 Short-term dietary toxicity to birds p. 579 ff

Vol 1 2.9.1.3 Sub-chronic and reproductive toxicity to birds p. 580 ff

Vol 19 B.9.1.1. Effects on birds p. 4 ff

Vol 19 B.9.1.4. Other data on effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians) p. 55 ff

The studies submitted were each carried out with only 10 birds instead of the required 20. In addition, these 10 were kept in a very small space (in some cases less than half as much as prescribed). Despite these conditions, the RMS tolerates the studies submitted by the applicant. The birds tested belonged exclusively to the order Galliformes and Anseriformes. Drawing conclusions from these larger birds to small songbirds does not seem feasible.

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Bees and non-target arthropods

Vol 3, B.9.3. EFFECTS ON ARTHROPODS pp. 468

The negative effects of glyphosate (GLY) and GLY-based herbicides (GHB) on non-target arthropods is mainly related to the disturbed or fully inhibited symbiosis with their microbiota. The consequences of morbidity must be assessed with time frames exceeding the 72h mark in Vol 3, B.9.3. Longer time frames are needed to gain a full understanding of the long-term effects of GLY on crucial pollinators. Studies related to indirect effects must be considered when assessing the renewal of GLY for their far-reaching implications, not only direct effects as in MON 52276. One study by Motta et al. (2020) on oral and topical exposure to GLY of honeybees found a disturbance of bee health and increased morbidity and mortality. The inhibition of the shikimate pathway via GLY and GHB changed the bee's gut microbial community via a reduction of beneficial bacteria. This was observed in a dose-dependent way and left these arthropods more vulnerable to infections due to a compromised immune response. Increased susceptibility to infection in insects after GLY/GHB exposition is also brought forward in a study by Smith et al. (2021) who further point out the relevance of melanin for arthropod immunity. Its production is also inhibited by GLY/GHB in addition to the adverse health effects from disturbed microbial symbiosis. Increased mortality has been observed in GLY/GHB-exposed caterpillars when faced with fungus infection. Kiefer et al. (2021) present another study on adverse effects of GLY/GHB on arthropod's nutritional endosymbionts: symbiont establishment in the host beetle was inhibited by GLY/GHB and negatively impacted cuticle growth and melanization, leaving arthropods with a weakened immune response. Overall, the adverse effects on endosymbionts of arthropods highlight an indirect but highly worrisome effect on non-target arthropods. Given accelerated declines in insect populations, glyphosate must not be granted reapproval in the EU.

Sources:

(1) Motta et al. (2020): *Oral or Topical Exposure to Glyphosate in Herbicide Formulation Impacts the Gut Microbiota and Survival Rates of Honey Bees*

(2) Smith et al. (2021): *Glyphosate inhibits melanization and increases susceptibility to infection in insects*

(3) Kiefer et al. (2021): *Inhibition of a nutritional endosymbiont by glyphosate abolishes mutualistic benefit on cuticle synthesis in *Oryzaephilus surinamensis**

Earthworms and other non-target soil macro- and mesofauna

Vol. 3, B.9.4. EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA p. 531 ff/Vol. 1, 2.9.9.4.1 Summary of risk assessment for earthworms p.703

For the conclusion of the RMS that an acceptable risk to earthworms when using MON 52276 can be expected, only three studies were used, two of which are not related to MON 52276, but on AMPA or to the active ingredient glyphosate itself. For the studies that have been submitted by the applicant, two different earthworm species were studied, both of which are among the so-called compost worms that live epigeal. In the studies, the compost worms were not fed dead plant

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material treated with glyphosate, but rather the animals were kept in substrate treated with glyphosate for the study. No negative effects could be found. There are 3,000 different earthworm species worldwide, 400 in Europe and almost 50 in Germany alone. Compost worms, as used in the studies, hardly occur in arable soils. Other species are found here. However, according to the results of the studies mentioned, the applicants do not even have to submit further tests under more realistic conditions. The studies carried out and required in this form by the competent authorities are not sufficient to determine the real risk that glyphosate poses for earthworms. There are numerous studies that show that glyphosate-containing agents do pose a risk to earthworms. In view of the great importance that earthworms have for maintaining soil fertility, among other things, they must be taken into account in the risk assessment. Furthermore, a revision of the requirements of the approval procedure for the direct and indirect effects of pesticides on earthworms is urgently needed.

Sources:

(1) Owagboriaye et al. (2021): "Impacts of a glyphosate-based herbicide on the gut microbiome of three earthworm species (*Alma millsoni*, *Eudrilus eugeniae* and *Libyodrilus violaceus*): A pilot study" (<https://doi.org/10.1016/j.toxrep.2021.03.021>)

(2) Zaller et al. (2014): "Glyphosate herbicide affects belowground interactions between earthworms and symbiotic mycorrhizal fungi in a model ecosystem" (DOI: 10.1038/srep05634)

(3) Gaupp-Berghausen et al. (2015): "Glyphosate-based herbicides reduce the activity and reproduction of earthworms and lead to increased soil nutrient concentrations" (DOI: 10.1038/srep12886)

Terrestrial non-target higher plants

Vol 1, 2.9.6 Summary of effects on terrestrial non-target higher plants p. 664 ff

Vol 1, 2.9.9.6 Summary of risk assessment for terrestrial non-target higher plants p 704 ff

Vol 29, B.9.11. Effects on terrestrial non-target higher plants p 328 ff

Vol 30, Part 7 References for assessment of indirect effects via trophic interactions for non-target terrestrial plants discussion p 84 ff

The studies that have been submitted by the applicant only investigate crop-plants. In this section, the risk for non-target higher plants in off-field situations is evaluated. It is therefore questionable why no studies concerning non-target plants have been submitted or included. In addition, studies concerning the off-field situation are completely missing. The submitted studies only investigate effects of glyphosate on crop-plants. Ferreira et al. (2017) determine glyphosate effects on over 20 native species, showing that some plant species die with very low rates while others are herbicide tolerant. These herbicide tolerant non-target plants could become established as new weeds. Glyphosate off-target drift could therefore promote the loss of biodiversity and the selection of new weeds. The risk to non-target plants is considered acceptable, when risk mitigations are implemented. These calculations regarding buffer zones did not take in account the influence of wind and rain for example (see point 4.04 Fate and behaviour in air). The German study "Pesticide pollution of the air" prove that glyphosate is transported through air for miles. As studies are missing, it is doubtful that the buffer zones provide sufficient protection. The effect of glyphosate in a forest was completely excluded from the evaluation. Here, glyphosate is used in order to reduce

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populations of plants competing with merchantable conifers. Golt et al. (2021) showed, that glyphosate has severe effects on reproductive morphology of *Rosa acicularis*, a highly prevalent understory shrub. These effects were still detectable two years after glyphosate application.

Sources:

(1) <https://www.sciencedirect.com/science/article/abs/pii/S0147651317303846>

(2) <https://www.frontiersin.org/articles/10.3389/fpls.2021.698202/full>

Other non-target terrestrial organisms (flora and fauna)

Vol. 3, B.9.6. EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS, p. 581ff

Glyphosate acts as a broad spectrum herbicide against all monocotyledonous and dicotyledonous plants. Broad spectrum herbicides not only destroy undesirable weeds, but also uncompetitive and rare wild herb species. The accompanying flora, which plays a key role in biodiversity in agricultural landscapes represents, is one of the most endangered species groups in Europe today.

Source:

https://www.bfn.de/sites/default/files/2021-04/20180131_BfN-Papier_Glyphosat.pdf

Other comments incl. Available monitoring data

Glyphosate is the most widespread herbicide not only in Germany, but worldwide. The use of glyphosate is associated with massive negative effects on biodiversity. These are difficult to measure. Nevertheless, particularly due to the immense extinction of species, they must be given a particularly high level of attention. In view of the ongoing extinction of species, especially insects, and the associated consequences for humans and the environment, further approval of glyphosate cannot be regarded as acceptable. The disadvantages associated with the application of glyphosate far outweigh any advantages. The German Federal Agency for Nature Conservation has described indirect effects on a large number of wild animals in agricultural landscapes. Through the use of glyphosate and the associated reduction in flowering wild herbs, the supply of flowers for insects in already cleared agricultural landscapes is further restricted. The food supply of herbivorous insects is also reduced in this way. The office also names negative indirect effects on earthworms with regard to their activity and reproduction. The decline in insects and earthworms, in turn, leads to a decline in the number of birds and small mammals that use these as a source of food. Mitigation measures such as buffer strips on bodies of water are not sufficient to reduce the risk to biodiversity to an acceptable level. The statements of the Federal Office including sources can be found here: https://www.bfn.de/sites/default/files/2021-04/20180131_BfN-Papier_Glyphosat.pdf A current study also shows how glyphosate also indirectly harms insects: It can inhibit symbiotic bacteria that are necessary for the formation of the exoskeleton of some species. This is evident from studies on beetles.

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Sources:

(1) <https://www.nature.com/articles/s42003-021-02057-6#Sec7>

(2) https://www.bfn.de/sites/default/files/2021-04/20180131_BfN-Papier_Glyphosat.pdf

General criticism

There is no room for general criticism in the consultation process. However, this could help to democratize and improve the process. That is why we would like to add general criticisms for which there is no classification and we ask for your attention.

1. Form of the documents provided, which were incorporated into the re-authorization procedure for glyphosate: Confusing presentation of the individual documents (with the enormous number of pages, this makes it extremely difficult to view and assess the data submitted);
2. In several cases, the documents are not machine-readable (in documents with a very large number of pages, there are always individual pages that are not machine-readable and therefore cannot be found in a keyword search, for example).

Selection of the public literature on the effects of glyphosate

The selection method of the public literature (non-industrial studies) and its classification as relevant or not relevant for the evaluation process must be viewed extremely critically. A study by the French NGO Generation Futures has shown that in the RAR only a negligibly small proportion of public studies on glyphosate were simultaneously classified as relevant and without restriction as reliable for the assessment of the herbicide, namely only 0.4% (30 of around 7,000) of the listed public studies. At the same time, industry studies that do not meet the requirements of the OECD guidelines were classified as acceptable.

Source:

<https://www.generations-futures.fr/wp-content/uploads/2021/11/evaluation-du-glyphosate-un-rapport-biaise-v4.pdf>

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Carcinogenicity

The International Agency for Research on Cancer (IARC) of the World Health Organization (WHO), tested the active ingredient glyphosate based on what was available to it (only publicly available studies) in 2015 and came to the conclusion that

- Glyphosate is "probably carcinogenic in humans" (carcinogen group 2A)
- there is sufficient evidence available that glyphosate is carcinogenic in laboratory animals

Furthermore, the IARC found a positive relationship between glyphosate and the occurrence of non-Hodgkin lymphoma (malignant lymph gland cancer that occurs in all Organs of the human body). The WHO classification is still valid and must urgently be taken into account.

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IARC: Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. Lancet Oncology, March 20, 2015,
<http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf>

Mutagenicity

1. The experts on genotoxicity (DNA damage) at the Institute for Cancer Research at the Medical University of Vienna Prof. Dr. Siegfried Knasmüller and Dr. Armen Nersesyan examined 53 studies of glyphosate DNA damage that were submitted by manufacturers as part of the previous approval process. Based on these studies, the European Food Safety Authority (EFSA) came to the conclusion that glyphosate is not genotoxic and with this classification contradicted the Cancer Research Agency of the World Health Organization (IARC), which classified glyphosate as genotoxic.

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It should not be repeated that studies have classified glyphosate as Non-DNA Damaging. The report of the Viennese experts must absolutely be taken into account and the studies submitted by the industry should be critically examined when in the last detail. Inadequate studies should not be accepted as reliable.

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<https://www.global2000.at/sites/global/files/Analyse-Glyphosat-Studien.pdf>

2. The International Agency for Research on Cancer (IARC) of the World Health Organization (WHO), tested the active ingredient glyphosate on the basis of that available to the organization (only publicly available studies) and came to the conclusion that

- Strong evidence of genotoxic effects from exposure to glyphosate
- Strong evidence of oxidative stress induction from exposure to Glyphosate, AMPA and based on glyphosate formulations

are present.

The genotoxic effect causes damage to the genetic make-up can trigger carcinogenic processes. Oxidative stress disrupts repair and detoxification function of the cells, which among other things can lead to DNA damage.

Source:

IARC (2015a): *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon, and glyphosate*. *Lancet Oncology*, March 20, 2015, [http://dx.doi.org/10.1016/S1470-2045\(15\)70134-8](http://dx.doi.org/10.1016/S1470-2045(15)70134-8)
<http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf>