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Frankfurt/Main, May 18th 2022

Attachment to the Open letter to the EU Commission

Regarding the current discussion of more advanced nonselective herbicide technologies in Europe, focus on Surfactants used in Glyphosate Based Herbicides

Dear Mrs. President Ursula von der Leyen Dear Mr. Timmermans Dear Mrs. Kyriakides DG SANTE Dear Mr. Sinkevicius DG ENV Dear Mr. Wojciechowski DG AGRI

The world's most widely used herbicide glyphosate in practice only come in contact with humans, plants and environment by means of Glyphosate Based Herbicides (GBH). Next to the active ingredient glyphosate, all GBH consist of so-called adjuvant packages with surfactants being the most important component thereof. These surfactants make the herbicide spread out and penetrate through the leaf surface.

Dating back since more than two decades, more and more scientific studies have highlighted that such glyphosate-based formulations with highly efficient surfactants often are significantly more genotoxic than glyphosate alone. In the Annex, please find just 10 such examples of scientific studies taken exclusively from the draft AGG-Report, the Commission has recently made available to the public for commenting.

First Robin Mesnage and Michael N. Antoniou brought it to the point in Frontiers in Public Health, 2018 Vol. 5, pp 361: "Ignoring Adjuvant Toxicity Falsifies the Safety Profile of commercial Pesticides". Only few months ago the same group of authors (see Annex) reported that EU-, UK- und US- representative GBH-formulations: "cause more biological changes linked with carcinogenesis than glyphosate".

During the recent Glyphosate Renewal Process, the Assessment Group Glyphosate (AGG, consisting of representatives from F, NL, HR and S) clearly stated: "The peer review recognized that the issue of toxicity of the formulations should be considered further as some published genotoxicity studies (not according to GPL or to OECD) on formulations presented positive results *in vitro* and *in vivo*. In particular, it was considered that the genotoxic potential of formulations should be addressed". (page 11 of the October 17, 2019 Pres Submission Meeting documentation)

For reasons we don't know, AGG gave up this request. They rather accepted the glyphosate manufacturer's counterproposal to use just one single "Representative Formulation MON 52276" to represent all Glyphosate-Based-Formulations offered in Europe. This proposal was based on one single sentence in the *EFSA 2019 Genotoxicity assessment of chemical mixtures* rule: "If the assessment of all components of a chemically fully defined mixture results in the conclusion that none of these raises a concern with respect to genotoxicity, the mixture is also considered of no



concern with respect to genotoxicity". However, the surfactants in this reference formulation are protected by trade secrets and hence were not and are not disclosed.

Due to this unacceptable situation we herewith respectfully ask the European Commission to initiate an <u>Investigation Program on the Safety of Surfactants in Glyphosate Based Herbicides.</u> This program should at least roughly classify among the numerous surfactants currently used in commercial GBH in Europe. Just three classes like:

- prohibited (e.g. POEA) or not recommended
- no objections known at present level of knowledge
- preferred at present level of knowledge

would already very much assist the national authorities which, according to EU-Regulation 1107/2009, are solely responsible for licensing Pesticide-Formulations. Also, this would help discourage foreign GBH-manufacturers to enter the European market with Non-State-of-the- Art-Products. Probably, such undertaking will encounter complex surfactant combinations and patent-issues. But public interest and safety concerns should prevail.

Until genetically modified crops will be available on the market which make herbicides unnecessary, agriculture will need at least limited amounts of GBH. European farmers should be sure to buy GBH which present the best possible compromise between efficiency, ecology and economy.

Yours respectfully,

Klaus - Peter faither

Prof. Dr. Klaus-Peter Jäckel, Chairman of the board "Senior Experts Chemistry" (SEC), section of the German Society of Chemistry (GDCh)

Prof. Dr. Klaus-Dieter Jany, Member of the SEC board

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Dr. Eckhart Louis, SEC – Member



With reference to the above explained situation that the safety profile of the active component glyphosate is not the same as the safety profile of a GBH, first please find below the report about threatening recent study results found at EU-, UK- and US reference formulations mentioned before and just 10 examples of scientific studies taken exclusively from the draft AGG-Report. These examples emphasize such additional negative impacts of surfactants and/or they compare different surfactants in this respect.

- R. Mesnage et al.;Comparative Toxicogenomics of Glyphosate and Roundup Herbicides by Mammalian Stem Cell-Based Genotoxicity Assays and Molecular Profiling in Sprague-Dawly Rats; Toxicological Sciences, Vol 186, Issue 1, March 2022, Pages 83-101
- 2- Vol. 3 B.4.4.3. Genotoxicity, pp 293-302; Nagy K. et al. highlighting significant differences between the impacts of ethoxylated etheralkylamine (CAS No. 68478-96-6) in "Roundup Mega" "hygroscopic substances" in "Fozat 480" polyethoxylated tallow amine (CAS No. 61791-26-2) in "Glyphos" to cyto- and genotoxicity in human cells; Environmental research (2019) Vol. 179, No. 108851, pp 1-7
- 3- Vol. 3 B.4.4.16. Public literature referenced in previous CLH report in vitro and in vivo genotoxicity studies pp 374-379; Bolognesi C. et al.; impact of surfactants, in particular alkylsulfate surfactants to various DNA damage in mice
- 4- Vol. 3 B.4.4.16. Public literature referenced in previous CLH report in vitro and in vivo genotoxicity studies page 379; Peluso M. et al.; ³¹P-Postlabelling Detection of Roundup DNA-Adducts were not related to the i-propylamine-glyphosate active ingredient but to another unknown component of the herbicide mixture
- 5- Vol. 3 B.6.5.18.7. Supporting publications p 226; Hao Y. et al. in Journal of Agriculture and food chemistry (2019) Vol. 67 No.41, pp 11346-372; presenting evidence that polyethoxylated Tallowamine promotes autophagy of human A549 cells
- 6- Vol. 3 B.6.6.3.1. Public literature relevant for section B.6.6.1. page 225; Gorga A. et al. in Toxicological sciences (2012) Vol. 127 No. 2 pp 391-402: Roundup Full II from Monsanto Argentina with undisclosed surfactant(s) and K-salt of glyphosate exhibits almost identical effects on Sertoli-cells of rats compared to the glyphosate-salt alone
- 7- Vol. 3 B.6.6.3. Reproductive Toxicity-Information from public literature page 235; Manservisi F. et al. in Environmental Health (2019) Vol. 18 No. 1 pp15; Roundup Bio Flow being identical with MON 52276 of undisclosed surfactant(s) has significantly stronger impact on reproductive outcomes in rats than the Glyphosate i-propylamine-salt alone
- 8- Vol. 3 B.6.6.3. Reproductive Toxicity-Information from public literature page 246; Pham T. et al. in Toxicological sciences (2019) Vol. 169 No. 1 pp 260-271; Roundup 3 Plus from Monsanto Europe with undisclosed surfactant(s) shows significant impact on reproductive parameters in mice compared to glyphosate 99,2% purity
- 9- Vol. 3 B.6.10-2a Overview of relevant but supplementary (category B) articles after detailed assessment page 796; DeFarge N. et al. in Int. J. Environ. Res. Public Health (2016) Vol. 13, pp 246; Co-formulants in GBHs with a broad variety of surfactants tested, incl, APGs (CAS No 383178-66-3), polyoxyethylene-etherphosphates (CAS No. 86130-47-2), polyoxyethylene-alkyletherphosphates (CAS No. 50769-39-6) and others disrupt Aromatase Activity in Human Cells well below levels of the active ingredient alone



- 10- Vol. 3 B.6.10-2a Overview of relevant but supplementary (category B) articles after detailed assessment page 797; Song H-Y et al. in Journal of Korean medical science (2012) Vol. 27 No.
 7; substantial differences in cellular toxicities between mixtures of glyphosate and surfactant POEA (Trade name NT 20) and glyphosate and surfactant polyoxyethylene laurylamine (Trade name NT 10)
- 11- Vol. 3 B.6.10-2a Overview of relevant but supplementary (category B) articles after detailed assessment page 816; Mesnage R. et al. in Toxicology (2013) Vol. 313 No. 2-3 pp 122; tests on human cell lines comparing systematically the different toxicities of POEAs with different di-ethoxylate/tallowamine ratios