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Framework for an inquiry committee on the renewal of the approval of Glyphosate

A Greens/EFA proposal

1. Allegation of failure by the Rapporteur Member State to carry out an independent, objective and transparent assessment in the light of current scientific and technical knowledge as required by Article 11(2) second subparagraph of Regulation (EC) No 1107/2009.

Justification: Key parts of the evaluation of the published scientific literature on genotoxicity, carcinogenicity and reproductive toxicity in the Renewal Assessment Report (RAR) prepared by the German Federal Institute for Risk Assessment (BfR) were not prepared by themselves, but were taken word for word from the approval application of the Glyphosate Task Force (GTF), but without indication of citations, giving the impression that this was their own assessment. An expert in plagiarism concluded that "*the writers of the report must be accused of significant scientific misconduct and of fulfilling all the definitional criteria of text plagiarism in the sense of conscious deception about the true authorship*". For most of these studies, GTF - and thus BfR - concluded that they are "unreliable" or "not relevant" for the EU assessment.

2. Allegation of failure by EFSA to properly use guidance documents available at the time of application with regard to the assessment of carcinogenicity as required by Article 12(2) second subparagraph of Regulation (EC) No 1107/2009.

Justification: EFSA did not act in accordance with OECD Guideline 116 by dismissing positive findings in trend tests. EFSA did not act in accordance with OECD Guideline 116 by dismissing statistically significant cancer findings in animal experimentation by establishing a limit dose.

3. Allegation of failure by the European Commission to apply the approval criterion of Article 4(3)(e)(ii) and (iii) of Regulation (EC) No 1107/2009 when granting the technical extension of the approval of Glyphosate in 2016 and when adopting Implementing Regulation (EU) 2016/1313 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate

Justification: Pursuant to Article 4(3)(e)(ii) and (iii) of Regulation (EC) No 1107/2009 "*a plant protection product ... shall meet the following requirements: ... it shall have no unacceptable effects on the environment, having particular to the following considerations where the scientific methods accepted by the Authority to assess such effects are available: ... (ii) its impact on non-target species ... (iii) its impact on biodiversity and the ecosystems*". Use of the non-selective herbicide glyphosate kills not only unwanted weeds, but all plants, as well as algae, bacteria and fungi, thereby having an unacceptable impact on biodiversity and the ecosystem. As such, the Commission granted a technical extension despite the fact that glyphosate fails to comply with point (e)(iii) of Article 4(3) of Regulation (EC) No 1107/2009.

EFSA found a high long-term risk for almost all uses of glyphosate for non-target terrestrial vertebrates, including mammals and birds. However, Implementing Regulation (EU) 2016/1313 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate does not contain any legally binding risk mitigation measures, let restrict any uses of glyphosate.

4. Allegation of failure by the European Commission to apply the precautionary principle pursuant to Article 13(2) of Regulation (EC) No 1107/2009 when granting the technical extension of the approval of Glyphosate in 2016 and when adopting Implementing Regulation (EU) 2016/1313 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate

Justification: Pursuant to Article 13(2) of Regulation (EC) No 1107/2009, the Commission shall take a decision on approval "On the basis of the review report, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 are relevant". Given the controversy over the classification of glyphosate, the conditions to apply the precautionary principle were clearly met, yet the

5. Allegation of failure by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) to properly apply the classification criteria of Point 3.6.2 of Annex I of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) with regard to the assessment of the carcinogenic nature of glyphosate

Justification: Pursuant to Point 3.6.2 of Annex I of Regulation (EC) No 1272/2008, a substance should be classified as a presumed human carcinogen (Category 1B) if there is sufficient evidence

in animal tests. Two or more tests are seen as sufficient. In the case of Glyphosate, there are at least three carcinogenicity studies that showed statistically significant cancer findings.

6. Allegation of maladministration by EFSA and RAC by failing to properly follow guidance on the application of the CLP criteria by dismissing a key study without any foundation and in an non-transparent manner

Justification: According to the CLP guidance by ECHA, "*The justification for dismissing any particular tumour should be presented as a scientifically robust and transparent argument.*"

EFSA and RAC rejected a key study (Kumar 2001) as unreliable due to the comment of an employee of

the US EPA during a telephone conference due to an alleged virus infection, which is however not reported in the study itself. The same employee is charged in an ongoing court case in the US with unduly influencing the cancer classification of glyphosate by the US authorities in the interest of Monsanto.

- https://www.global2000.at/sites/global/files/Expert%20Opinion%20Glyphosat%20Plagiarism%20English.pdf
- https://echa.europa.eu/documents/10162/23036412/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5

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