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Commission nationale DAspe
Déontologie et Alertes en santé publique et environnement

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Opinion on the conditions for public confidence in the the evaluation process for the renewal of the authorisation of glyphosate in Europe.

Deliberated on 16 December 2021 in plenary meeting, approved on 23 December 2021

In the context of the mission entrusted to it by law to ensure the deontology of scientific and technical expertise in support of public actions and policies in the field of health and the environment, the cnDAspe is issuing this opinion.

Considering the following background information:

1- The French government's commitment in 2018 to a process of phasing out glyphosate[1], with an initial objective of reducing its use in France by 50% by 2022.

2- The resolution adopted by the European Parliament on 9 June 2021 *on the EU Biodiversity Strategy 2030: Bringing nature back into our lives*[2], which expresses strong concern that "*nature is deteriorating at a rate and scale unprecedented in human history*", but *that* "it is *not too late to halt and reverse the current trend of biodiversity decline*".

3- The Inserm collective expertise report "*Pesticides and health effects. New data*", published in June 2021[3], which includes a section on glyphosate and glyphosate-based formulations. The experts' analysis of published scientific data indicates that "*new data strengthen the presumption of a link between glyphosate and the risk of Non-Hodgkin's Lymphoma* in *farmer populations*" and that, as this is one of the main mechanisms involved in the development of cancer, "*the number of experimental studies showing genotoxic effects is much greater than those not showing genotoxic effects*". The Inserm report also observes that "*there is a time lag between the fundamental questions of biology on the mechanisms of action of toxicity, in particular on mitotoxicity* [toxicity on mitochondria*],*

1 https://agriculture.gouv.fr/pourquoi-sortir-du-glyphosate

2 https://www.europarl.europa.eu/doceo/document/TA-9-2021-0277_FR.html

3 https://www.inserm.fr/expertise-collective/pesticides-et-sante-nouvelles-donnees-2021/

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and the tools validated by the regulatory agencies, which could partly explain certain controversies, in particular on glyphosate.

4- The pre-report made public in June 2021 by the four rapporteur states (France, Hungary, the Netherlands and Sweden) responsible for the re-evaluation of glyphosate[4] (whose current authorisation period ends in December 2022). This document states that the classification of this herbicide as carcinogenic, mutagenic or reprotoxic (within the meaning of Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures) is not justified, either as an active substance in its own right or in the formulations of Round Up that are consistent with those submitted in the renewal dossier. This pre-report also states that glyphosate does not fall under the criteria for endocrine disruption (as defined in Regulation (EC) No 1107/2009 as amended by Regulation (EU) No 2018/605).

5- The very strong selection of scientific articles and dossiers on which the reporting states would have relied to produce the conclusions of the pre-report made public in June 2021, within a voluminous scientific information base exploring the toxic and ecotoxic risks of glyphosate and its formulations. The pre-report states that "*The studies required in a dossier are defined in EU legislation and in guidance documents and technical guides. All studies must be conducted in accordance with Good Laboratory Practice (GLP) in accredited laboratories. [...] In addition to these studies, public scientific literature is also taken into account in the assessment. All public scientific literature older than ten years prior to the submission of the dossier must be formally and transparently searched. The literature search strategy is described in the draft renewal assessment report. The literature is sorted by relevance and, where appropriate, summarised and evaluated. [For all relevant literature, reliability was assessed. For example, toxicological studies where the dose administered or the formulation used was not (correctly) reported were generally not considered (fully) reliable. It should be noted that studies reported in the public literature are often not conducted according to GLP*. According to an analysis produced in the context of the public consultation opened by EFSA on this pre-report (and closed on 22 November), around 90% of the articles published in the international scientific literature were eliminated as being "irrelevant", which means that the material considered would mainly consist of dossiers submitted by industrialists applying for renewal of the authorisation[5], as these industrial studies are conducted in accordance with GLP as defined by the OECD Guidelines and recommended by the regulations on plant protection products. Among

4 https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/glyphosate/assessment-group_fr

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

the dossiers retained for evaluation, a high proportion would have already been considered during the previous re-evaluation of glyphosate in 2013-2017.

6- The publication in July 2021 by A. Nersesyan and S. Knasmuelle, renowned researchers in genetic toxicology, of a report carried out on behalf of the NGO SumOfUs, which asserts the unreliability of the vast majority of the dossiers on which the experts from the rapporteur state (Germany, the Slovak Republic being the co-rapporteur state) as well as EFSA [6]and ECHA[7] relied during the last evaluation of glyphosate in 2017. This report[7] was made possible by a judgment of the European Union General Court of 7 March 2019[8], which, when seized by MEPs, ordered EFSA to provide access to the industry's files on the genotoxicity of glyphosate, which had previously been kept secret. After reading the documents obtained in this way, the researchers found that the industry data did not themselves comply with the OECD guidelines, which are supposed to be a major criterion for assessing the existing literature. This conclusion is likely to raise serious doubts in the public mind about the impartiality of the experts who made the judgement. Far from responding to these concerns, EFSA refused to publish the names of the Member State experts involved in the scientific assessment and their declarations of interest.

7- The recent report of the Expert Group "*Chemical Risk Management*" [9]which is based on an analysis of the strengths and weaknesses of the hazard and risk assessment procedures for active substances and plant protection products in the context of the EU regulation and the marketing authorisation process in the Member States. The report contains 12 recommendations, including in particular recommendation 11 to "*Diversify the experimental models required in and for the regulation of the hazard assessment of chemical*

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6 EFSA: European Food Safety Authority; ECHA: European Chemical Agency

7 https://s3.amazonaws.com/s3.sumofus.org/images/Evaluation_scientific_quality_studies_genotoxic_glyphosate.pdf

In fact the draft "renewal assessment report" is dated 18 December 2013, and its public version was published by EFSA on 12 March 2014. The review of the renewal application was delayed by 3 years due to the difference in the respective conclusions of IARC on the one hand and EFA and ECHA on the other

8 https://curia.europa.eu/juris/document/document.jsf;jsessionid=9C71000ADF3ADF736548BD9A3A1CFE46?text=&docid=211426&pageIndex=0&doclang=FR&mode=req&dir=&occ=first&part=1&cid=24002344

9 https://www.alerte-sante-environnement-deontologie.fr/IMG/pdf/211020_cndaspe_gt_risque_chimique_rapport.pdf

substances". According to these experts, the only tests prescribed by the OECD Guidelines, conducted according to "Good Laboratory Practice" (GLP) with the aim of standardisation, simplification and reproducibility, have major flaws in exploring the complexity of several categories of toxic and ecotoxic effects, and are even limited in their ability to characterise carcinogenic potential.

8- The opinion of the cnDAspe[10], following the report "*For an alert management of the chemical risk*", which recommends in particular the establishment of a procedure at Community level which allows a more transparent and thorough examination of the conditions for recourse to safeguard clauses by a Member State in the event of serious doubt, based on recent scientific data on the risks which may result from the exposure of living species to plant protection products which have been granted a marketing authorisation

Responsible by law for monitoring the ethical rules applying to scientific and technical expertise and aware of the importance of increasing citizens' confidence in the expertise carried out within the European Union on public health and the environment, the CNDAspe recommends to the Government, as France holds the rotating presidency of the European Union during the first half of 2022:

1- To propose to its partners and to the European Commission the constitution of an international panel of independent personalities [11]specialised in the ethics of scientific expertise in the fields of the environment and public health, with the task of examining the links of interest of each of the experts who are members of the committees that participated in the pre-report of the rapporteur States on glyphosate, which has been made public in June 2021, as well as of the experts who are going to take part in the Community peer review process within the EFSA and ECHA bodies A similar retrospective analysis of the evaluation process conducted between 2013 and 2017 would also be necessary. On the basis of the findings, this independent panel could make recommendations to the European and national authorities with a view to strengthening the prevention of conflicts of interest among experts contributing to Community expertise processes in the fields

10 https://www.alerte-sante-environnement-deontologie.fr/deontologie-et-alertes-en-sante-publique-et-environnement/travaux/avis-rendus/article/avis-accompagnant-la-publication-du-rapport-du-groupe-d-experts-independants

11 Independence is defined here in relation to stakeholders with an interest in the use of plantprotection products [PPPs] and their active substances in agriculture and forestry (organisations grouping together manufacturers, importers or users of PPPs; civil society organisations advocating for or against this use; administrations in charge of public policies in the fields of agriculture, the environment or health) and in relation to national or Community bodies involved in the expertise processes on PPPs and their active substances in general.

of the environment and public health and the transparency of the procedures followed for such expertise. The report of this independent panel should be made public.

2- To ask the European Commission that before any examination by EFSA and ECHA of the pre-report submitted by the four rapporteur states, a critical analysis be carried out by an international panel of independent[11] personalities specialised in toxicology in the field of cancer, genotoxicity, reprotoxicity and endocrine disruption, as well as in ecotoxicology, on the process of systematically reviewing the scientific articles and dossiers that were taken into consideration to assess the totality of the available evidence and finally retained to form the basis of the position of the evaluation panel addressed to EFSA in June 2021. This independent panel would verify that this process is in line with the methods set out in the regulations for the selection and analysis of scientific data for the hazard identification and risk assessment of plant protection active substances. It could also formulate recommendations for the evolution of this regulatory framework in order to take into account the rapid evolution of scientific knowledge. The report of this independent panel should be made public.

These two assessments of the impartiality and methodological rigour of the expert opinions are now essential if European citizens are to have confidence in and accept the conclusions of the current process of assessing the possible risks to life from the use of glyphosate.