20 October 2015

Mr. Vytenis Andriukaitis
Commissioner Health & Food Safety
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels
Belgium

By email only

(Cc to Mr. Ladislav Miko, Action Director-General, DG Health & Food Safety, and Bernhard Url, Executive Director, EFSA)

Open letter:
EFSA peer review of the renewal assessment report (RAR) on glyphosate by the BfR

Dear Commissioner Andriukaitis,

We are writing to you as we are concerned about the ongoing peer review of the renewal assessment of the active substance glyphosate in the context of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market in the European Union. In March 2015, the WHO Agency for Research on Cancer (IARC) announced its classification of glyphosate as "probably carcinogenic to humans". The corresponding monograph was published in July 2015.[1] The Commission requested the European Food Safety Agency (EFSA) in April 2015 to consider the findings by IARC as regards the potential of carcinogenicity of glyphosate or glyphosate containing products in the ongoing peer review. We welcome this request.

However, since March there has been much debate on the question of how and why the German competent authority, the Federal Institute for Risk Assessment (BfR), acting for the rapporteur Member State Germany, came to a very different conclusion than IARC. BfR continues to consider that glyphosate would not be carcinogenic, most recently at a hearing in the German Parliament on 28th of September.

Several experts had a closer look at BfR's risk assessment report – see e.g. the written statements for the hearing[2] and a recently published report[3]. One of these experts was a member of the so-called "JMPR Expert Taskforce on Glyphosate". This task force was established to recommend to JMPR (Joint FAO/WHO Meeting on Pesticide Residues) how to proceed, taking into account the strong divergence between JMPR's evaluation of glyphosate, which is comparable to BfR's conclusions, and

[1] http://monographs.iarc.fr/ENG/Monographs/vol112/
[2] http://www.bundestag.de/bundestag/ausschuesse18/a10/anhoerungen/anhoerung_glyphosat_28_09_2015/386986
[3] http://blog.campact.de/2015/09/studien-zur-krebsgefahr-von-glyphosat-verschwiegen/

the recently published IARC assessment. In September 2015, the task force came to the conclusion that a full re-evaluation of glyphosate on the FAO/WHO level would be necessary, noting that many studies, mainly from the published peer-reviewed scientific literature, were not considered in the former JMPR reports (2004 and 2011) on glyphosate[4]. Leading author of both JMPR reports was a staff member of BfR[5].

The BfR risk assessment report constitutes the basis for the EU risk assessment of glyphosate. However, a considerable list of open questions regarding the quality and reliability of BfR's risk assessment arose from the work of these experts (see appendix).

We are convinced that it is indispensable to address all open questions thoroughly before any further decision is taken concerning the re-approval of glyphosate. Therefore, we ask you to ensure that EFSA fully addresses these issues listed in the appendix in the context of its current peer review – and that clear answers to these questions are made publicly available.

If additional time was needed for that, this should not be a problem, as the current authorization of glyphosate was recently extended to the end of June 2016. As such, there is enough time to fully consider all open questions without any need for further delays regarding the re-approval decision.

In this context, we consider that two aspects are of particular concern: genotoxicity and human evidence. IARC found "strong evidence" for genotoxic effects of glyphosate – while BfR found no evidence at all for such effects "under normal exposure scenarios". Given that genotoxic substances are normally considered to be non-threshold substances, it is of crucial importance to properly assess the potential genotoxicity of glyphosate.

Secondly, BfR recently stated that it also found "limited evidence" for cancer-causing effects in humans – only to dismiss these findings arguing that epidemiological studies concern the formulation instead of the active substances alone and would therefore not be relevant. However, we would consider this to be incompatible both with the letter of the law as well as the mandate you have given to EFSA. According to Article 4(5) of the Regulation on Plant Protection Products, for the approval of an active substance, the approval criteria need to be satisfied for at least one or more representative uses of at least one plant protection product containing that active substance. And in your request to EFSA, you clearly refer to the potential of carcinogenicity of glyphosate or *glyphosate containing products* to be assessed.

We therefore urge you to ensure that all relevant data with regard to glyphosate and the use of glyphosate containing products, including epidemiological data, are fully considered by EFSA in its peer review.

Moreover, we are greatly concerned that the Commission asked EFSA in its request from April 2015 to consider "whether a **firm causality** can be established between the phenomena observed in IARC's assessment and the application of glyphosate containing plant protection products consistent with good plant protection practice and having regard to realistic conditions of use" (own emphasis added).

We consider that the request for a "firm causality" not only has no basis in Regulation (EC) No. 1107/2009, but could moreover undermine the letter and the spirit of the law. The legislator clearly decided that an active substance that is carcinogenic shall only be approved, if it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B. According to that Regulation, a substance may be classified as Category 1B based

[4] http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/
[5] http://apps.who.int/pesticide-residues-jmpr-database/pesticide?name=GLYPHOSATE

on animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity. There is no requirement whatsoever to prove that the effects found in animal experiments also occur in the field, let alone establish a "firm causality" between the carcinogenicity found in animal experiments and the application of the glyphosate containing plant protection product in the field.

The classification alone triggers the regulatory consequences. An approval of a carcinogen is only possible if the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, or pursuant to the derogations laid down in Article 4(7), but not based on any other considerations.

We urge you to clarify that there is no need for EFSA to establish a "firm causality" between the application of glyphosate in agriculture and cases of cancer in the population in order to recommend a classification in category 1B ("presumed to have carcinogenic potential for humans, classification is largely based on animal evidence") **according to the CLP regulation. IARC, as one of the most trusted names in Cancer Hazard Evaluation, found "sufficient evidence" for glyphosate causing cancer in experimental animals and "limited evidence" for cancer causing effects in humans. At this level of hazard assessment any request for a "firm causality" as a potential prerequisite for classification or further consequences is inadequate.**

Yours sincerely,

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