Alliance for
Cancer Prevention

4 June 2015

Mr Ladislav Miko
Acting Director-General
Directorate-General for Health and Food Safety
Rue Breydel 4/Breydelstraat 4
B-1049 Brussels

By email only

Commission request to EFSA regarding IARC findings on glyphosate

Dear Mr Miko,

We are writing to express some concerns regarding the scope of the Commission's request to the European Food Safety Authority (EFSA) to consider, in their ongoing peer review, the findings by IARC as regards the potential carcinogenicity of glyphosate or glyphosate-containing plant protection products.

We are pleased to see that you have asked EFSA to "investigate the carcinogenic potential of glyphosate raised by IARC". We also think it is right that EFSA should, based on this investigation, consider "whether an amendment of the original proposal as regards classification of glyphosate is necessary".

However, we are concerned that the scope of the request is too narrow for EFSA to deliver an analysis that can fully inform the further decision-making process.

(1) DG SANTE's request to EFSA to consider "whether a firm causality can be established" between the phenomena observed in IARC's assessment and the application of glyphosate products is inappropriate.

IARC has classified glyphosate as "probably carcinogenic to humans" (Class 2A), not as "carcinogenic to humans" (Class 1). It has found "limited evidence of carcinogenicity in humans" as well as "sufficient evidence of carcinogenicity in experimental animals", but not "sufficient evidence of carcinogenicity in humans". We therefore believe that it is unrealistic to expect that EFSA will establish "a firm causality" between human exposure and the development of cancer when IARC did not.

In our view, EFSA should be tasked to fully investigate all evidence of causality between human exposure to glyphosate and the development of cancer, and not specifically "a firm causality". It is up to EFSA to evaluate the weight of evidence and to recommend an appropriate classification under Regulation 1272/2008. Telling EFSA to only look for "a firm causality" would unduly narrow its task and potentially render it meaningless vis-à-vis the EU regulatory process.

(2) That EFSA is asked to consider the application of glyphosate products "consistent with good plant protection practice and having regard to realistic conditions of use" contradicts EU legislation.

The EU classification as a carcinogen applies to "substances which have an intrinsic property to cause cancer" (Regulation 1272/2008, Annex I). The classification is therefore independent of the level and type of human exposure.

Regulation 1107/2009 stipulates that, if the substance is classified as a carcinogen category 1A or 1B, it cannot be approved in the EU unless, "under realistic proposed conditions of use", it is used "in closed systems or in other conditions excluding contact with humans" (Regulation 1107/2009, Annex II). We are not aware of any conditions of use that would rule out any human exposure, even under "good plant protection practice". Therefore, the precise conditions of use, and whether "good plant protection practice" is being complied with, are irrelevant to the EFSA assessment.

In the light of these concerns, we are asking you to consider a revision of the EFSA request. Please can you confirm that the intention is not to limit the scope of EFSA's work in the ways outlined above so that its findings can allow an informed debate about the future of glyphosate in the EU.

In view of the public interest in this matter we will make this letter available on our websites.

Yours sincerely,

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