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Mr Ladislav Miko
Deputy Director-General for Food Safety
DG Health and Food Safety
European Commission
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Subject: Response to your request for a statement following the further publication of documents related to Monsanto and glyphosate ("Monsanto papers")

Dear Mr. Miko,

Thank you for your letter dated 10 August 2017 in which you request a statement from ECHA concerning the further publication of documents related to Monsanto and glyphosate¹ (the so-called "Monsanto papers") and their impact on the overall assessment and conclusions of ECHA on the classification and labelling of glyphosate. In particular, comment was sought on an *in vitro* percutaneous absorption study and related documents.

Based on the careful assessment of the information contained in the recently released additional "Monsanto papers", ECHA can confirm that they did not have any impact on the overall hazard assessment as presented in the Opinion on the proposed harmonised classification and labelling (CLH) of glyphosate that was discussed and adopted by the Committee for Risk Assessment (RAC) on 15 March 2017.

The CLH process is concerned exclusively with the assessment of hazardous properties of a substance (not risks associated with its use). Information on dermal absorption is primarily used to address risks associated with the use of the substance. Dermal absorption studies, including the TNO study in question are not relevant to the assessment carried out by RAC and it is not surprising therefore that the latter was not summarised in the CLH report on glyphosate or in the attachment accompanying the CLH report (or the "Renewal Assessment Report Addenda"). This study could have had no possible influence on the RAC conclusions on any of the hazards assessed, including carcinogenicity.

ECHA notes that with the recently released additional "Monsanto papers", a series of emails has received extensive attention in which there is discussion between authors prior to the publication of a review article by Williams *et al* (2016)². As noted in our statement dated June 2017³, this article was considered by RAC (having been brought to RAC's attention

¹ <https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/monsanto-secret-documents>

² Williams GM, Aardema M, Acquavella J, Berry C, Brusick D, Burns MM, de Camargo JLV, Garabrant D, Greim HA, Kier LD, Kirkland DJ, Marsh G, Solomon KR, Sorahan T, Roberts A, Weed DL (2016). A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment. *Critical Reviews in Toxicology*, 46:sup1, 3-20.

³ https://echa.europa.eu/documents/10162/22431146/echa_statement_regarding_assessment_of_glyphosate_en.pdf/2d4acbad-37e1-a6cf-7fef-f78711768b75 and https://echa.europa.eu/documents/10162/22431146/annex_echa_statement_regarding_assessment_of_glyphosate_en.pdf/58ddda6b-c1da-3dae-91d8-612efd0676de

during the process), along with all the other available information. However, it was not deemed sufficiently influential to merit a reference in the opinion. Throughout the opinion forming process, RAC relied on the considerable number of studies summarised in the CLH report that have been performed in accordance with agreed (internationally standardised) methodology and quality requirements (OECD or equivalent technical guidelines and good laboratory practice (GLP)). Original study reports were made available to enable RAC to verify the findings reported. Review articles, even if they were to provide relevant information, are given the lowest weight in the CLH process. This issue has been addressed in some detail in our previous response.

In summary, the dermal absorption study referred to in the recently released additional "Monsanto papers" was not considered by RAC and in general studies addressing the properties of formulations are normally not useful for addressing the hazardous properties of substances. Throughout the opinion forming process, RAC relied on the considerable number of OECD guideline and GLP-compliant studies summarised in the CLH report to form its own independent conclusion.

If you need further information on this matter or on any other aspect of the assessment of the harmonised classification of glyphosate by the RAC, please do not hesitate to contact me.

Yours sincerely,

SIGNED

Geert Dancet
Executive Director