

From: [REDACTED]@monsanto.com>
Sent: 17 May 2016 18:17
To: [REDACTED] (SANTE)
Subject: RE: JMPR May 2016 - Glyphosate

Dear [REDACTED], dear [REDACTED],

In the context of Article 56 of Regulation 1107/2009 and in the context of the upcoming ScoPAFF discussions on glyphosate (May 18-19), the Glyphosate Task Force would like to inform you about the following new information on glyphosate:

The "**Joint Meeting on Pesticide Residues**" (JMPR) is an expert ad hoc body administered jointly by **FAO and WHO** in the purpose of harmonizing the requirement and the risk assessment on the pesticide residues. The JMPR has met annually since 1963 to conduct scientific evaluations of pesticide residues in food. It provides advice on the acceptable levels of pesticide residues in food moving in international trade. The JMPR consists of experts who attend as independent internationally-recognized specialists who act in a personal capacity and not as representatives of national governments.

The current JMPR comprises the **WHO Core Assessment Group** and the **FAO Panel of Experts on Pesticide Residues in Food and the Environment**. The WHO Core Assessment Group is responsible for reviewing pesticide toxicological data and estimating Acceptable Daily Intakes (ADI), acute reference doses (ARfDs) and characterizes other toxicological criteria.

The active ingredient 'Glyphosate' was scheduled for re-evaluation at the **2016 extraordinary meeting of the JMPR**, based on recommendations of the JMPR 2015. Probably the most robust toxicology data package on glyphosate, including data considered by the IARC and data considered by US, Japanese and European regulators, was reviewed by the panel.

During its 'extraordinary meeting', recently organized in Geneva (9-13 May 2016), the JMPR has concluded that glyphosate is "**unlikely to pose a carcinogenic risk to humans from exposure through the diet.**" (<http://www.who.int/foodsafety/jmprsummary2016.pdf?ua=1>).

The JMPR's conclusion is consistent with the overwhelming consensus of regulatory authorities around the world and builds on the recent science-based conclusions by the European Food Safety Authority (EFSA) and the Canadian Pest Management Regulatory Authority (PMRA). In fact, in just the 13 months since IARC classified glyphosate, regulatory authorities in Europe, Canada, Japan and Australia have all publicly reaffirmed that glyphosate is unlikely to cause cancer. In addition, the October 2015 report of the U.S. EPA's Cancer Assessment Review Committee also concluded that glyphosate is classified as "Not Likely to be Carcinogenic to Humans."

Kind regards,

[REDACTED] on behalf of the Glyphosate Task Force
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From: [REDACTED]
Sent: 11 August 2015 09:41
To: [REDACTED]
Subject: RE: Publication IARC Monograph on glyphosate

Dear [REDACTED],

As communicated to you earlier, a panel of the International Agency for Research on Cancer (IARC) classified glyphosate as a Category 2A, “probable human carcinogen”, under its criteria and interpretation of their ‘potential carcinogenicity hazard identification’ system. On March 20, 2015 the IARC panel published a short summary opinion in the News section of the Lancet Oncology (Vol 16. No 5, pp. 490-491, March 2015), generating significant media attention and public confusion regarding the status and safety of glyphosate globally. On July 29, 2015, IARC published their 92 page monograph containing the details - not included in the Lancet- the panel had considered for glyphosate and their considerations in reaching this conclusion (<http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-02.pdf>).

The GTF trusts that the 2A classification reached under the IARC principles of potential hazard identification will not be confirmed under the more robust principles of regulatory hazard characterization where (1) all available relevant information is considered, where (2) general principles of toxicology evaluation are honored (e.g. acceptance of historical control data, critical assessment of relevance, reliability, repeatability and experimental design of experiments etc), and where the weight of evidence is valued and considered in the context of toxicology classification.

Indeed, during the ongoing European regulatory evaluation of glyphosate all available relevant information (including the data considered by IARC) has been considered and evaluators have explicitly stated they found no grounds to classify glyphosate for carcinogenicity to date. Given the GTF's technical assessment of the IARC monograph (summarized below and detailed in the attachment to this message), the GTF trusts the IARC opinion is not going to impact the regulatory classification conclusion. The latter will need to be confirmed in the EFSA conclusions on glyphosate expected late October this year.

In the GTF's opinion safety datasheet information on glyphosate does not need to be adjusted at this time.

HIGHLIGHTS FROM PRELIMINARY REVIEW OF THE IARC MONOGRAPH ON GLYPHOSATE BY GTF EXPERTS

- IARC's monograph does not present new research data

The IARC monograph is not a 'study'. It does not contain or consider new or original data on the hazard, exposure or risk of glyphosate. All the key studies considered by IARC in their monograph have been previously reviewed and considered by regulatory agencies, most recently in the context of a comprehensive toxicology assessment by the EU Rapporteur Member State and by the Canadian PMRA for the re-registration processes in the EU and Canada respectively, neither of which found glyphosate to pose a carcinogenic risk.

- Unlike regulatory agencies, IARC did not consider the total weight of evidence available for glyphosate

It is clear from the limited references listed in the monograph that the information actually selected for consideration by the IARC panel represents only a subset of the vast dataset available on glyphosate. Consideration of the complete dataset, as done by regulators globally, overwhelmingly supports the conclusions of safety and lack of carcinogenic potential of glyphosate.

- IARC selected data points and made very basic errors in data interpretation within each of the four areas of evidence they considered (animal carcinogenicity, exposure, genotox and epidemiology). The most striking highlights are given below.

1. Animal Carcinogenicity: In reaching their conclusion of 'sufficient evidence' of carcinogenicity in animals, the IARC panel reinterpreted isolated findings of tumor incidences in particular studies, focusing on numerical increases in tumor incidence in treatment groups but ignoring the lack of a dose-response, background tumor incidences in historical control animals and pathology expert opinions –all of which typically provide context to toxicologists in their assessment whether there is a possible relationship to treatment. IARC's approach is non-standard and at odds with basic toxicology practices. Other experts and regulators have long concluded that all the isolated tumors discussed by IARC were spontaneous and not related to glyphosate treatment. Moreover, multiple other long-term studies conducted according to international standards were not reviewed by IARC but clearly corroborate the lack of carcinogenic potential of glyphosate.

2. Exposure : The IARC monograph considered an incomplete literature review, citing old references where more recent and relevant ones exist, reflecting current glyphosate uses and reflecting more reliable exposure studies and analytical detection methods. The Monograph appears to selectively use references and data. IARC cites detections of glyphosate into different matrices (urine, serum, soil, air, water and food) without putting the levels and potential exposures into the proper context. In reality Regulatory authorities and the JMPR establish ADIs and/or AOELs to account for potential human exposures and establish safety exposure levels. When exposure is put into the proper context it is consistently concluded that there are no health concerns with the exposure to glyphosate.

3. Genotoxicity: In reaching their conclusion of strong evidence that glyphosate and commercial formulations can be genotoxic and produce oxidative damage, the IARC panel selectively relied on non-standard studies with adverse effects, which used methods that have not been validated and/or not conducted according to international guidelines. Furthermore IARC disregarded a plethora of more relevant data, peer reviewed literature reviews, and opinions of numerous other scientists who have carefully considered all the available data and concluded glyphosate is not genotoxic.

4. Epidemiology: In reaching their conclusions of Limited evidence in humans for the carcinogenicity of glyphosate, IARC used Case-control studies with design limitations and diverse methods for the estimation of glyphosate exposure and an inappropriate statistical model. IARC ignored the findings of the largest and single most important study into the health of pesticide applicators in the US which found no link between glyphosate and non-hodgkin's lymphoma or any other cancer.

With this message the GTF wants to meet its commitment to you of providing a technical analysis of the IARC Monograph. In case you have further questions comments or needs please don't hesitate to contact me.

Kind regards,

[REDACTED] on behalf of the Glyphosate Task Force

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From: [REDACTED]
Sent: 29 July 2015 17:38
To: [REDACTED],
Subject: Publication IARC Monograph on glyphosate

Dear [REDACTED],

As you know, the active substance **glyphosate** (CAS 1071-83-6) was the subject of a review by the International Agency for Research on Cancer (IARC) as part of its 'Meeting 112' (Lyon, March 3-10, 2015).

Subsequently, the IARC panel published its opinion in *The Lancet Oncology on March 20th*. In its hazard assessment IARC classified glyphosate as a Category 2A, "probable" human carcinogen.

With this message, Monsanto would like to inform you that **today** the IARC published its Monograph on glyphosate, outlining the methodology and analysis that underpins its hazard classification: <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-02.pdf>.

Monsanto communicated its disagreement with the IARC hazard classification to you in March and, irrespective of IARC's hazard classification, we would like to emphasize that the risk assessment of plant protection products, including the assessments of glyphosate's safety for humans, is the responsibility of the national regulatory authorities who have reviewed the comprehensive weight of evidence available.

Nevertheless, the European Glyphosate Task Force will study the IARC monograph in detail and would be pleased to provide you with our initial assessment within the coming week.

Please don't hesitate to contact me if you have questions or comments.

Best regards,

[REDACTED] on behalf of the Glyphosate Task Force

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