

International Agency for Research on Cancer



150 cours Albert Thomas
69372 Lyon cedex 08, France

Office of the Director
Tel.: +33 4 72 73 85 77
Fax: +33 4 72 73 85 64
E-mail: director@iarc.fr
<http://www.iarc.fr>

Dr Bernhard Url
Executive Director
European Food Safety Authority (EFSA)
Via Carlo Magno 1A
I-43126 Parma

E-mail: bernhard.url@efsa.europa.eu;
ed.directorate@efsa.europa.eu

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CPW/mg

5 February 2016

Dear Dr Url,

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans

I am following up on our telephone conversation of 25 January 2016 and your kind offer to correct any misrepresentations of the IARC Monographs on the EFSA website and in distributed materials.

In your letter and Annex dated 13 January 2016, responding to Dr Christopher Portier on the topic of glyphosate, the IARC Monographs are repeatedly referred to as a first step or "screening" assessments. This could easily be misconstrued as preliminary or superficial, and it is important therefore that this impression is corrected.

In fact, the IARC Monographs are widely recognized as an authoritative standard for cancer hazard assessment around the world. Far from being "screening" assessments, they are comprehensive evaluations based on systematic assembly and review of all publicly available studies. The classification follows objective evaluation criteria and a uniform, hierarchic evaluation structure that is consistent across assessments (please see the [IARC Monographs Preamble](#)). Transparency, openness and scientific independence are assured throughout the evaluation process. Importantly, pertinent competing interests of meeting participants are publicly disclosed prior to the evaluation and are accessible in the final, fully referenced Monograph (for glyphosate see the [IARC Monographs on Some Organophosphate Insecticides and Herbicides](#)).

In the Annex to this letter we have detailed some examples of the changes EFSA would need to make in order to achieve accurate, balanced and complete communication about this important cancer hazard identification programme and its specific analysis of glyphosate.

My opinion is that timely correction of all factual errors and misrepresentations with respect to the IARC Monographs is necessary, as an indication of good faith, before we can confirm the planned joint meeting between EFSA and IARC. Moreover, in this spirit of openness and friendly cooperation, we can assure the European Commissioner for Health and Safety Dr Vytenis Andriukaitis, following his recent visit to IARC, that both institutions are seeking to work towards better regulations and health, in Europe and globally.

I thank you again for your constructive offer to act on the errors mentioned above and look forward to your response.

With best regards,

Yours sincerely,



Christopher P. Wild, PhD
Director

ENCL.: Annex "Corrections requested from EFSA"

cc:

Dr Vytenis Andriukaitis, European Commissioner for Health and Food Safety
(vytenis.andriukaitis@ec.europa.eu; cab-andriukaitis-webpage@ec.europa.eu)
Mr Phil Hogan, European Commissioner for Agriculture and Rural Development
(phil.hogan@ec.europa.eu)
Mr Xavier Prats Monné, Director-General for Health and Food Safety, EC (xavier.prats-
monne@ec.europa.eu)
Dr Ladislav Miko, Deputy Director-General for Food Safety, EC (ladislav.miko@ec.europa.eu)
Dr Giovanni La Via, Chair, European Parliament Committee on the Environment, Public Health
and Food Safety (ENVI) (giovanni.lavia@europarl.europa.eu)
Mr Christian Schmidt, German Federal Minister of Food and Agriculture (poststelle@bmel.bund.de)
Dr Helmut Tschiersky, President, German Federal Office of Consumer Protection and Food Safety
(helmut.tschiersky@bvl.bund.de; poststelle@bvl.bund.de)
Dr Andreas Hensel, President, German Federal Institute for Risk Assessment (leitung@brf.bund.de)
Mr Jim Jones, Assistant Administrator, US Environmental Protection Agency (jones.jim@epa.gov)
Dr Christopher J. Portier, for a group of 96 independent academic and governmental scientists
from 25 countries (cportier@me.com)
EFSA Panel on Plant Protection Products and their Residues (pesticides.ppr@efsa.europa.eu)
Mr David Allen, Director of Administration and Finance, IARC (allend@iarc.fr)
Dr Kurt Straif, Head, Section of IARC Monographs (straifk@iarc.fr)

Annex: Corrections requested from EFSA

Fact Sheet, EFSA Explains Risk Assessment, Glyphosate

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf

The following references to IARC are inaccurate or imply criticism which is not justified and we request deletion:

“IARC assesses generic agents”

“EFSA assessed more evidence including additional key studies that were not considered by IARC”.

“...the IARC report looked at both glyphosate – an active substance – and glyphosate-based formulations, **grouping all formulations regardless of their composition.**” Delete “grouping all formulations” from this sentence.

“This distinction between active substance and pesticide formulation mainly explains the differences in how EFSA and IARC weighed the available data.”

Reply to C Portier and Annex

http://www.efsa.europa.eu/sites/default/files/EFSA_response_Prof_Portier.pdf,

The following references to IARC or the Monograph on glyphosate are factually incorrect or imply criticism of the IARC evaluation. We request therefore that the IARC Director’s letter to Dr Url and this associated Annex are posted on the EFSA website alongside the exchange of letters between Professor Portier and EFSA.

- “...we should not compare this first screening assessment with the more comprehensive hazard assessment done by authorities such as EFSA” (letter p 1)
- All references to the IARC Monographs as a “screening assessment” (letter p 1 and throughout) and other language suggesting the Monograph evaluation is preliminary.
- “Comprehensive description and evaluation of the new long-term studies by the RMS in its Renewal Assessment Report was not taken into consideration by IARC even though this information was publicly available from April 2014” (Annex p 5).
- “...five additional valid long-term toxicity-carcinogenicity studies known of but not assessed by IARC...” (Annex p 6-7)”.
- “...no assessment of a sex-related mechanism is provided in the IARC assessment” (Annex p 6-7).
- “The IARC monograph reports for several studies significant body weight reductions at the highest doses, which are in fact the doses triggering the statistical significance of the trend analysis” (Annex p 7).
- e) Conclusion (Annex p 10). Delete sentences beginning with “In contrast” to end of paragraph.
- “...there is no indication in the Monograph of any attempt to establish the possible role of the co-formulants, even when other studies (in vitro or in animals) report negative effects for the active substance and positive effects for the formulated products.” (Annex p 11).
- “IARC did not try to differentiate whether the effects were linked to the active substance, other ingredients (co-formulants), or combined effects of several ingredients, even when the evidence suggested negative effects for glyphosate and positive effects for a formulated product.”