European Food Safety Authority

EXECUTIVE DIRECTOR

09 FEB 2016

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Dr. Christopher Wild
Director
International Agency for
Research on Cancer
150 cours Albert Thomas
69372 Lyon cedex 08,
France

Re: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans

Ref.: Your letter dated 5 February 2016

Dear Dr. Wild,

I refer to your letter of 5 February 2016 in which you raise concerns about the way in which EFSA refers to the IARC Monographs on our website.

Firstly, please allow me to reassure you that EFSA recognises the important contribution IARC makes to the assessment of cancer hazards and to the high scientific standards set by the IARC Monograph programme. It is for precisely this reason that EFSA's evaluation of glyphosate was postponed as this enabled us to consider the findings of the IARC assessment in our own work. It is also why we invited IARC to take part as observers in EFSA's expert discussions prior to adopting our conclusions.

Please also allow me to reassure you that by referring to the IARC Monographs as a first step or "screening assessment" in our response letter to Dr Christopher Portier on 13 January 2016 we in no way meant to imply criticism or to characterise the Monographs as superficial. These references stem from IARC's own description of the Monographs that can be found on the IARC website: "The *Monographs* represent the first step in carcinogen risk assessment..." and "The *Monographs* are used by national and international authorities to make risk assessments" [original emphasis][1]. The purpose of these references was merely to draw attention to the fact that EFSA operates in a specific regulatory context and that the scope and objectives of the EFSA and IARC hazard assessments are different and not directly comparable.

This also explains why we state on our website the fact that EFSA assessed more evidence than IARC. Here we refer to the mandatory Good Laboratory Practice studies that applicants must submit according to EU pesticides legislation and that EFSA and EU Member States appraise, not all of which were considered by IARC in its assessment of glyphosate.

[1] http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php

Regarding your concern about the phrase "IARC assesses generic agents", this was inferred from the IARC Monograph Preamble which states that the term 'agent' "refers to any entity or circumstance that is subject to evaluation in a *Monograph*" and may include "specific chemicals, groups of related chemicals, complex mixtures, occupational or environmental exposure, cultural or behavioural practices, biological organisms and physical agents"[2].

Regarding the other specific statements by EFSA that you refer to in your letter, again these are not intended as criticisms of IARC but rather represent EFSA's scientific view based on our review of the evidence in the IARC Monograph on glyphosate. EFSA and IARC may have differences of opinion about these issues but it was my understanding that we had agreed to meet in February precisely in order that we could discuss these differences in more detail and, where possible, seek to explain them.

With this in mind – and given the high level of public concern about glyphosate – I strongly believe that there is value in going ahead with the planned meeting between EFSA and IARC. Not only will it allow for an in-depth scientific discussion among our experts, I also believe that a face-to-face meeting is the best way to address any remaining misunderstandings between our two organisations, which inevitably are difficult to avoid through written communication alone. I hope that you share this view in line with the spirit of openness and friendly co-operation that you refer to in your letter.

I am happy to publish this exchange of letters on our website and, should you agree, the minutes of the planned meeting next week which would provide space to set out any divergent views the two organisations may have about the science behind glyphosate. Following the meeting, I would obviously be willing to correct any factual mistakes about IARC on our website should these remain.

Finally, beyond the specific issue of glyphosate, we are of course also open to a future discussion on how to improve co-ordination between regulatory agencies such as EFSA and the various WHO bodies involved in the assessment of regulated compounds, such as pesticides.

Yours sincerely,

Bernhard Url

cc (email only):

Dr. Vytenis Andriukaitis, European Commissioner for Health and Food Safety

Mr. Phil Hogan, European Commissioner for Agriculture and Human Development

Mr. Xavier Prats Monné; Director-General, European Commission DG Health and Food Safety

Dr. Ladislav Miko, Deputy Director-General, European Commission DG Health and Food Safety

[2] Ibid

Dr. Giovanni La Via, Chair, ENVI Committee of the European Parliament

Mr. Christian Schmidt, German Federal Minister of Food and Agriculture

Dr. Helmut Tschiersky, President, BvL

Prof. Dr. Dr. Andreas Hensel, President, BfR

Mr. Jim Jones, Assistant Administrator, USEPA

Dr. Christopher J. Portier; Senior Contributing Scientist, Environmental Defence Fund

Mr. David Allen, Director of Administration and Finance, IARC

Dr. Kurt Straif, Head, Section of IARC monographs, IARC

EFSA Panel on Plant Protection Products and their Residues