

EXHIBIT 117

From: Kurt Straif <StraifK@iarc.fr>
To: Keith Solomon <ksolomon@uoguelph.ca>
Cc: "David.Collingridge@lancet.com" <David.Collingridge@lancet.com>, "Blair, Aaron (NIH/NCI) [V]" <blaira@exchange.nih.gov>
Bcc:
Date: Wed, 17 Jun 2015 21:28:43 +0000
Subject: RE: Genotoxicity of glyphosate in humans

Dear Dr Solomon,

Thank you for your comments concerning the interpretation of your paper "Biomonitoring of genotoxic risk in agricultural workers from five Colombian regions: association to occupational exposure to glyphosate".

Evaluations of carcinogenicity for the IARC Monographs are made by Working Groups of recognized experts, who are charged with identifying, reviewing and interpreting the relevant scientific literature. In the course of reviewing a particular study, it sometimes happens that the Working Group reaches different conclusions than the authors or places greater weight on different parts of the data. We regard this as a strength of the evaluation process, which brings the group's collective expertise to bear on the review of all the published evidence.

This was the case with your paper, where the Working Group found the comparisons of the frequencies of micronucleated cells before and after spraying to be particularly informative, while your interpretation emphasised other results.

Given that the foregoing differences are ones of interpretation, rather than of fact, we do not envision any correction to the Lancet Oncology report or the conclusions it presents.

Further, the data from your study were not viewed as establishing a causal relationship. Rather, as summarized in The Lancet Oncology, the accumulated data from mechanistic studies were seen as lending strong support to the classification of glyphosate as probably carcinogenic, which rests on sufficient evidence of carcinogenicity in studies of cancer in animals and limited evidence of carcinogenicity in epidemiologic studies of cancer in humans.

Sincerely

Kurt Straif, MD PhD MPH
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From: Keith Solomon [mailto:ksolomon@uoguelph.ca]
Sent: 15 June 2015 03:14
To: imo@iarc.fr; blaira@mail.nih.gov
Cc: Gabriel Carrasquilla
Subject: Genotoxicity of glyphosate in humans

Dear IMO and Dr Aaron Blair

Attached and copied below is a letter to IARC and specifically to Panel 112 on the genotoxicity of glyphosate in humans. Please bring this to the attention of the Panel.

14 June 2015

IARC Monographs Section

IARC, 150 Cours Albert Thomas,

69372 Lyon CEDEX 08, France

imo@iarc.fr

blaira@mail.nih.gov

Re: Guyton KZ, Loomis D, Grosse Y, El Ghissassi F, Benbrahim-Tallaa L, Guha N, Scoccianti C, Mattock H, Straif K. 2015. Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. *The Lancet Oncology* DOI:10.1016/s1470-2045(15)70134-8:

Dear IMO and Dr Aaron Blair

I am writing on behalf of Dr Gabriel Carrasquilla and myself as co-authors of a paper² that was incorrectly quoted and/or misinterpreted to show that formulated glyphosate was genotoxic in humans. Our study "*Biomonitoring of genotoxic risk in agricultural workers from five Colombian regions: Association to occupational exposure to glyphosate*"¹ was conducted at the request of and funded by the Organization of American States (OAS). When this work was conducted, Dr Carrasquilla and I were working under contract to the CICAD office of the OAS. I was the leader of the Scientific Advisory Team and Dr Carrasquilla was the Colombian coordinator of the projects and, as an epidemiologist, was leader of the epidemiology component and the experimental design for this biomonitoring study. Dr Bolognesi is a world authority on micronuclii and, in collaboration with a laboratory in Bogota, provided the staining and microscopic analysis. Several studies were undertaken as part of this project; this paper was one of them and all are published in *J. Toxicol. Environ. Hlth. A.*, 2009, **72**. 913 ff.

The purpose of our study was to test the hypothesis that proximity to or contact with glyphosate spray used in agriculture and to control the growth of the coca plant (*Erythroxylum* spp.) in Colombia resulted in changes in the frequency of binucleated leucocytes with micronuclei (BNMN) in subjects from five regions with different use-patterns of glyphosate.

There were increases in the frequency of BNMN in the sprayed regions after application of glyphosate. However, in contrast to what Guyton et al.² and the Panel appear to have deduced, this does not constitute causal evidence that the BNMN resulted from exposure to glyphosate. The Bradford Hill viewpoint³ of biological gradient (dose-response) was not fulfilled in data from Valle del Cauca, where a lower rate of application of glyphosate was linked to an increased frequency of BNMN. In addition, the viewpoint of consistency was not fulfilled in recent reviews of *in vitro* and *in vivo* studies on genotoxicity that included our work and concluded that glyphosate was not genotoxic.^{4, 5}

Further, as this was an ecologic study, we recognized that the subjects would not necessarily all be exposed directly to the spray used for control of coca, even in the sprayed regions. The timing of the spraying was not known to the subjects so we included questions in a post-spray survey to collect "*Specific information about exposure at the time of aerial spraying in Putumayo, Nariño, and Valle del Cauca...*"¹. These questions were designed to better characterize exposures in the subjects and were asked within 4 days of the spray event, when exposures would have been accurately recalled.

Further evidence of a lack of biological gradient is provided in Table 4 and in the conclusions of our paper¹, "*There was no significant association between self-reported direct contact with eradication sprays and frequency of BNMN. The frequency of BNMN in participants who self-reported that they were exposed to glyphosate because they entered the field immediately after spraying (to pick the coca leaves), felt spray drops in their skin, or they thought they were exposed because they had contact with the chemical in the air, was not significantly greater than in subjects living in the same areas but who were not present during spraying*".

We realized and explicitly stated in our paper that the subjects could be exposed to many other agents that might affect the frequency of BNMN. These agents might have included other pesticides used in agriculture or chemicals and solvents used to extract leaves of coca plants picked just after spraying. These other activities that were temporally linked to spraying might be responsible for changes in frequency of BNMN. However, the study was not designed to answer these questions; the focus was on proximity to or contact with the glyphosate spray only.

Our data do not support the causal relationship of genotoxicity of glyphosate in humans that Guyton et al.² and IARC Panel 112 appear to have concluded. It appears that the Panel did not consider all of the information in the paper. We trust that this error will be corrected and any conclusions based on this error will be revised.

- 1 Bolognesi C, Carrasquilla G, Volpi S, Solomon KR, Marshall EJP, 2009, Biomonitoring of genotoxic risk in agricultural workers from five Colombian regions: Association to occupational exposure to glyphosate, J. Toxicol. Environ. Hlth. A., 72, 986-997.
- 2 Guyton KZ, Loomis D, Grosse Y, El Ghissassi F, Benbrahim-Tallaa L, Guha N, Scoccianti C, Mattock H, Straif K, 2015, Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate, The Lancet Oncology, DOI:10.1016/s1470-2045(15)70134-8.
- 3 Hill AB, 1965, The environment and disease: association or causation?, Proc. R. Soc. Med., 58, 295-300.
- 4 Kier LD, Kirkland DJ, 2013, Review of genotoxicity studies of glyphosate and glyphosate-based formulations, Crit. Rev. Toxicol., 43, 283-315.
- 5 Kier LD, 2015, Review of genotoxicity biomonitoring studies of glyphosate-based formulations, Crit. Rev. Toxicol., 45, 209-18.

Sincerely

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