

Message

From: [Redacted]
Sent: 2/20/2015 12:32:47 AM
To: SALTMIRAS, DAVID A [Redacted]
Subject: FW: [Redacted] et al. (2015) [Redacted] (2015) summaries, abstracts and sound bytes

David,

I think I might have misunderstood something in our earlier conversation today but apparently the Summary and Sound bytes were from Monsanto.

Please consider the bcc: comments I sent earlier to Roger. While I definitely support glyphosate and GBF's I really don't want to have inappropriate absolutes representing this review.

Thanks.

[Redacted]

From: Roger McClellan [Redacted]
Sent: Thursday, February 19, 2015 5:21 PM
To: [Redacted]
Cc: DAVID A [Redacted] SALTMIRAS; [Redacted]
Subject: Re: [Redacted] (2015) summaries, abstracts and sound bytes

Larry:

What I forwarded to T and F [Redacted] is what I received from David Saltmiras. I assumed you were in the loop on what had been developed at Monsanto. I suggest you get in touch ASAP with David. In the mean time I will ask T and F to let me review whatever they develop prior to its release. IF T and F does something to publicize the two papers I suspect it will be very brief.

Thanks for your input.

Roger

On Thursday, February 19, 2015 5:12 PM,

Redacted

wrote:

Dear Dr. McClellan (Roger):

I'm a little cautious about high levels of publicity for the biomonitoring review and have concerns about some of the suggested publicity material.

I don't know who wrote the "Summary" for my paper and certainly don't want to offend them but it is not the way I would have worded it and I would personally not want this used to characterize my paper. I have a revision below but I don't know whether these summaries are appropriate for publication authors:

Summary

A recent review examined several studies that measure damage to the DNA (genotoxicity) in cells collected from people exposed to pesticides including glyphosate-based herbicides. The author concluded that these studies do not indicate significant genotoxic risks to humans from glyphosate-based herbicides under normal exposure conditions. These findings are consistent with an earlier review of an extensive number of laboratory studies that indicated little likelihood of significant genotoxic risk or reaction with DNA under normal exposure conditions.

I also don't think the "Sound bytes for social media" are accurately worded. They are way too absolute for my taste and place undue emphasis on the strength of the biomonitoring study data. Unfortunately, I can't readily suggest alternatives that fit nicely into the "sound byte" format.

Frankly, the biomonitoring studies that are informative for GBF exposure were few in number (arguably 5) and the robustness of the results is pretty low (not unexpected for biomonitoring studies). My conclusion, as stated, was that the limited data from biomonitoring studies do not contradict the much more extensive and robust data from experimental studies that suggest no significant genotoxic risk or DNA-reactive mechanism, especially under expected much lower actual real-world exposures compared to experimental exposures. I would personally place much more emphasis on the experimental study data but the Summary and particularly the "Sound bytes for social media" don't do this and place undue emphasis on the strength of the biomonitoring

data. This focus is understandable for publicity directed at the biomonitoring study but I still am not comfortable with this.

Please note that I believe this qualification applies particularly to the biomonitoring review and I support a stronger conclusion regarding low genotoxic risk from glyphosate and GBF's based on the experimental study review.

Thanks very much for the communication and please let me know if I can be of further assistance.

Redacted

From: Roger McClellan; **Redacted**
Sent: Thursday, February 19, 2015 3:43 PM
To: **Redacted**
Cc: DAVID A **Redacted**; SALTMIRAS; Mildred; Claire; Roger McClellan; **Redacted**
Subject: Fw: **Redacted** (2015) summaries, abstracts and sound bytes

Publicity for Glyphosate Papers

Charles:

I spoke to David Saltmiras today concerning the two Glyphosate papers that will be the lead papers in the next issue of Critical Reviews in Toxicology with regard to F and F putting out any publicity on these two papers. The e-mail below includes complete citations for the papers, abstracts and some information developed by Monsanto Company on the papers.

As you may be aware, these papers have been forwarded to the International Agency for Research on Cancer (IARC) in Lyon, France. IARC at a meeting in early March will be considering the carcinogenic hazard classification of Glyphosate and some other phosphate containing agricultural chemicals. These papers will be a topic of discussion at that meeting. IARC will announce its carcinogenic hazard classification for all the chemical agents reviewed at the meeting, this will probably be done at a Press Conference on March 10. A brief paper describing the results of the meeting will also be published within a few weeks after the meeting concludes. A large Monograph documenting the reviews will be published in early 2016.

As a bottom line the two papers published on line in CRT are likely to attract some attention in the scientific and regulatory community and, possibly, by lay media. I am uncertain as to the policy of T and F on publicizing articles published in Journals such as CRT. If T and F is doing so, these two articles would be excellent candidates.

Please let me know your views on this matter and how you plan to proceed. Let me know if I can be assistance.

On a related matter, I am uncertain as to how T and F would like to handle access to these two papers. I suspect that Monsanto would be interested in purchasing "open access" if that is an option.

Best regards,

Roger

On Thursday, February 19, 2015 1:16 PM, "SALTMIRAS, DAVID A" wrote:

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Roger – FYI on press releases.

Redacted D. Saltmiras, V. Mostert, and **Redacted** 2015. Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies. *Crit. Rev. Toxicol.* In press

Summary: A new scientific publication examining 14 separate cancer studies in rats and mice conducted over the last several decades concludes that there is no evidence that glyphosate, the active ingredient in Roundup branded herbicides, causes cancer. The article, in *Critical Reviews in Toxicology*, evaluated the data from these long term studies to determine whether there were any patterns to suggest humans exposed to

glyphosate would have any concern about developing cancer. Other scientifically relevant information such as expert regulator evaluations, human dietary exposures and epidemiological studies were also discussed. The clear and consistent view across over 30 years of relevant information continues to support the first expert opinions from the 1980's, that glyphosate does not cause cancer.

Abstract: Glyphosate, an herbicidal derivative of the amino acid glycine, was introduced to agriculture in the 1970s. Glyphosate targets and blocks a plant metabolic pathway not found in animals, the shikimate pathway, required for the synthesis of aromatic amino acids in plants. After almost forty years of commercial use, and multiple regulatory approvals including toxicology evaluations, literature reviews, and numerous human health risk assessments, the clear and consistent conclusions are that glyphosate is of low toxicological concern, and no concerns exist with respect to glyphosate use and cancer in humans. This manuscript discusses the basis for these conclusions. Most toxicological studies informing regulatory evaluations are of commercial interest and are proprietary in nature. Given the widespread attention to this molecule, the authors gained access to carcinogenicity data submitted to regulatory agencies and present overviews of each study, followed by a weight of evidence evaluation of tumor incidence data. Fourteen carcinogenicity studies (nine rat and five mouse) are evaluated for their individual reliability, and select neoplasms are identified for further evaluation across the data base. The original tumor incidence data from study reports are presented in the online data supplement. There was no evidence of a carcinogenic effect related to glyphosate treatment. The lack of a plausible mechanism, along with published epidemiology studies, which fail to demonstrate clear, statistically significant, unbiased and non-confounded associations between glyphosate and cancer of any single etiology, and a compelling weight of evidence, support the conclusion that glyphosate does not present concern with respect to carcinogenic potential in humans.

Sound bytes for social media:

- New scientific review examines over 30 years of data, concludes glyphosate does not cause cancer in animals and poses no cancer risk to humans
- Over 30 years of data: no evidence that glyphosate causes cancer
- New glyphosate scientific review: over 30 years of data, demonstrates it does not cause cancer in animals and poses no cancer risk to humans

Redacted Review of Genotoxicity Biomonitoring Studies of Glyphosate-Based Formulations.
Crit. Rev. Toxicol., in press

Summary: A recent review examined several studies that allege damage to the DNA in cells collected from people after self-reported exposures to glyphosate-based herbicides. The author concluded that there are no

direct risks to human DNA under normal exposure conditions. These findings are consistent with an earlier review of an extensive number of laboratory studies that also demonstrated no direct effect on DNA. Taken together, these results confirm previous conclusions that glyphosate-based herbicides do not damage DNA in humans following real world exposures.

Abstract: Human and environmental genotoxicity biomonitoring studies involving exposure to glyphosate-based formulations (GBFs) were reviewed to complement an earlier review of experimental genotoxicity studies of glyphosate and GBF's (Kier and Kirkland, 2013). The environmental and many of the human biomonitoring studies were not informative because there was either a very low frequency of GBF exposure or exposure to a large number of pesticides. One human biomonitoring study indicated no statistically significant correlation between frequency of GBF exposure reported for the last spraying season and oxidative DNA damage. Negative results for the lymphocyte cytokinesis-block micronucleus (CBMN) endpoint were observed in a second human monitoring study with exposure to several pesticides including GBF. There were three studies of human populations exposed to GBF aerial spraying. One study found increases for the CBMN endpoint but these increases did not correlate with self-reported spray exposure or application rates. A second study found increases for the blood cell comet endpoint at high exposures causing toxicity. However, a follow-up to this study two years after spraying did not indicate chromosomal effects. The results of the biomonitoring studies do not contradict an earlier conclusion derived from experimental genotoxicity studies that typical GBF's do not appear to present significant genotoxic risk under normal conditions of human or environmental exposures.

Sound bytes for social media:

- New analysis of human data: glyphosate-based herbicides do not damage cellular DNA following realistic human exposures
- Human data: glyphosate-based herbicide following realistic human exposure not associated with DNA damage in human cells

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Science Fellow

Novel Chemistry and Microbials Product Lead
Toxicology and Nutrition Center
Monsanto

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