

Message

From: GOLDSTEIN, DANIEL A [Redacted]
Sent: 10/6/2015 5:07:40 PM
To: Cohen, Samuel M [Redacted]
Subject: FW: Glyphosate and Prop 65- SAM COHEN
Attachments: Prop 65 Background.docx; Prop 65 Letter SC- draft.docx; IARC Glyphosate mono112-02.pdf; IARC Monograph Review August 5 2015 pdf.pdf

Sam-

Apologies that I was not able to get this out yesterday. I wanted to provide you a draft letter and I was under the impression that a model letter was available, but this was not the case (we had models, but not appropriate to your expertise). I consequently had to pull one together.

The model letter is intended to provide the *pro-forma* content needed for transmission of the letter (fyi...NOIL = Notice of Intent to List in Cal-Speak) and to provide suggested content to minimize the work on your end given your schedule. You are obviously free to comment entirely as you wish and to change the letter in any way that suits your opinion.

I know you have specific opinions about the IARC process itself, and you should feel free to express them. I have limited my draft comments to factual information as I do not feel it is appropriate for me to attempt to draft comments on IARC itself.

I have attached a brief backgrounder on Prop 65 as well as the Monograph and an internal review of the Monograph. NOTE - I am happy to provide any of the background documents that you may want to see including summary documents (Greim review, Kier review, etc.) and original publications- speak and you shall receive!

As a final note- the labeling of glyphosate products, especially the concentrates, is probably a given as this is (my understanding) written into Prop 65 language and driven automatically off of the IARC 2A classification. Your input on the broader issue will nonetheless be very important as OEHHA will need to consider the "safe harbor" rules around diluted product and, more importantly, food and beverages. We do not currently believe that food residues would justify labeling of foods but there is apparently some room for OEHHA discretion in that area.

Your help is tremendously appreciated. Contact me if you need anything.

Best regards- Dan

From: FARMER, DONNA R [AG/1000]
Sent: Monday, October 05, 2015 3:25 PM
To: GOLDSTEIN, DANIEL A [AG/1000]; HEYDENS, WILLIAM F [AG/1000]
Subject: RE: Glyphosate and Prop 65- SAM COHEN

Correct attachments this time.

Yes that one was written for the ITO contacts to edit and send as they saw fit.

It was the only one I had so I thought it would work.

From: GOLDSTEIN, DANIEL A [AG/1000]
Sent: Monday, October 05, 2015 3:21 PM
To: FARMER, DONNA R [AG/1000]; HEYDENS, WILLIAM F [AG/1000]
Subject: RE: Glyphosate and Prop 65- SAM COHEN

Sorry- missed the 2nd attachment.....

I assume we want them to edit the letter as desired and then sign...

Dan

From: FARMER, DONNA R [AG/1000]
Sent: Monday, October 05, 2015 2:54 PM
To: GOLDSTEIN, DANIEL A [AG/1000]; HEYDENS, WILLIAM F [AG/1000]
Subject: FW: Glyphosate and Prop 65- SAM COHEN
Importance: High

From: GOLDSTEIN, DANIEL A [AG/1000]
Sent: Friday, October 02, 2015 2:57 PM
To: FARMER, DONNA R [AG/1000]; HEYDENS, WILLIAM F [AG/1000]
Subject: FW: Glyphosate and Prop 65- SAM COHEN
Importance: High

Please see below-

SAM CAN DO THIS BUT WANTS MATERIAL MONDAY OR TUESDAY-

Do we have draft correspondence?? I assume I can send him the monograph and share our summary of the analysis.

Do we have suggested commentary of any sort?? In particular- do we have a comment we want him to make on the food labeling issue vs labeling of product???

I have discussed this topic (and the subject of IARC in general) with Sam and he is a strong supporter.

Dan

From: Cohen, Samuel M [Redacted]
Sent: Friday, October 02, 2015 2:53 PM
To: GOLDSTEIN, DANIEL A [AG/1000]
Subject: RE: Glyphosate and Prop 65

I would be willing to do this, as long as you can get the material to me by Monday or Tuesday.

From: GOLDSTEIN, DANIEL A [AG/1000] [Redacted]
Sent: Friday, October 02, 2015 2:40 PM
To: Cohen, Samuel M
Subject: Glyphosate and Prop 65

L'shana tovah- I hope this finds you well. Knowing you are busy, I will keep my request brief.

As you probably are aware, IARC has classified glyphosate as a probable human carcinogen. The process for the meeting was highly irregular, and the outcome flies in the face of EPA and the new EU risk assessment. Because IARC is a default driver of California Prop 65 labeling, **glyphosate is now being considered for Prop 65 labeling. A public comment period extends through October 20.**

QUESTION: Would you be willing to consider submitting a comment to OEHHA regarding carcinogenicity classification of glyphosate?

If you are willing to consider this, I am happy to send you the IARC monograph and a summary of same with commentary, as well as a pro-forma letter with the proper address, etc. so that you do not need to dig out the

procedural information. Your comments, obviously, would be your own- but this would minimize the effort needed on your part.

Please let me know if you would be willing to look at this material.

Thanks as always! Dan

Daniel A. Goldstein, M.D.

FAAP, FACMT, FRCP(C), DABCP

Senior Science Fellow

Lead, Medical Sciences and Outreach

Monsanto

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California's Office of Environmental Health Hazard Assessment (OEHHA) recently announced its intention to add glyphosate to the state's Proposition 65 (Prop 65) list. Prop 65, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986, was approved by California voters in 1986 and requires the state to publish a list of "chemicals known to the state to cause cancer." Monsanto strongly disagrees with this listing.

OEHHA's **sole basis** for proposing to include glyphosate on Prop 65 list is the classification of glyphosate as a Category 2A "probable carcinogen" earlier this year by the International Agency for Research on Cancer (IARC). Specifically, because IARC stated there was "sufficient evidence" of carcinogenicity in animals, OEHHA is proposing to use its authority under the California Labor Code to rush through a decision to add glyphosate to the Prop 65 list, as it has done with many other chemicals. OEHHA does not conduct any new research or studies as part of this process.

Monsanto has joined with others in the industry to voice strong disagreement with the IARC classification as well. IARC did not present any new research or data; it did not consider the total weight of scientific evidence available on glyphosate; and it selectively used data points and made basic errors in data interpretation.

Key Messages:

- For more than 40 years, glyphosate-based herbicides have been a valuable tool for weed control for landscaping and lawn care professionals, farmers and other users in California. All labeled uses of glyphosate are safe for human health and the environment and supported by one of the most extensive worldwide human health databases ever compiled on an agricultural product. Our goal is to ensure that any potential listing will not affect the availability of glyphosate in California.
- No regulatory agency in the world considers glyphosate to be a carcinogen. Regulatory agencies around the world have concluded that all labeled uses of glyphosate are safe for human health and the environment. In the United States, the EPA has placed glyphosate in its most favorable category for carcinogenicity. Glyphosate's history of safe use is supported by decades of data from more than 800 scientific studies – many conducted by independent researchers.
- As it has with hundreds of other substances over the years, including aloe vera, the California Office of Environmental Health Hazard Assessment (OEHHA) recently announced its intention to list glyphosate under the strict provisions of Proposition 65.
- The **sole basis** of OEHHA's intention to list is the classification of glyphosate earlier this year by the International Agency for Research on Cancer (IARC). OEHHA interprets Prop 65 to allow it to simply accept the IARC classification without further scrutiny or review. OEHHA does not evaluate the weight or quality of the evidence considered by IARC.
- Monsanto and others in the industry strongly disagree with the IARC classification. The IARC classification overlooked decades of thorough and robust analysis by regulatory agencies, including a multi-year assessment just completed on behalf of the regulatory authority in the European Union. Another registration review is currently underway by the U.S. EPA. The IARC classification is based on a limited hazard identification approach and does not consider real-world use and exposure, which is a key element of the thorough risk assessments conducted by regulatory agencies.
- For more information about glyphosate safety, please visit [monsanto.com/glyphosate](https://www.monsanto.com/glyphosate).

Ms. Esther Barajas-Ochoa, Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010
Fax: (916) 323-2265

[INSERT DATE]

Regarding: *NOIL Glyphosate*

Ms. Barajas-Ochoa,

Please accept these comments in opposition to the Office of Environmental Health Hazard Assessment's (OEHHA) intention to list glyphosate under the Labor Code provision of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

Glyphosate-based herbicides are among the most thoroughly tested in the world. Their history of safe use is supported by one of the most extensive worldwide human health, crop residue and environmental databases ever compiled on a pesticide product.

The International Agency for Research on Cancer's (IARC) misclassification of glyphosate should not be used by OEHHA to list glyphosate under Prop 65. It is based on a limited and selective use of data without consideration of established toxicological principles which are key elements of the thorough risk assessments conducted by global regulatory agencies. Regulatory authorities and independent experts around the world have reviewed numerous long-term carcinogenicity and genotoxicity studies and agree that there is no evidence that glyphosate causes cancer, even at very high doses, and that it is not genotoxic. IARC overlooked decades of thorough and robust analysis by regulatory agencies, including a multi-year assessment just completed on behalf of the pesticide regulatory authority in the European Union.

The IARC monograph does not present new research or data. All the key studies considered by IARC in their monograph have been previously reviewed and considered by regulatory agencies, most recently in 2015 in a more 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.

IARC did not consider the total weight of scientific evidence available for glyphosate. It is clear from the limited references listed in the monograph that the information actually selected for consideration by the panel represents only a subset of the data available on glyphosate. Evaluation 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, genotoxicity, and epidemiology); for example:

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 of whether there is a possible relationship to treatment. IARC's approach is non-standard and at odds with basic toxicological 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 long-term toxicology 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 ones exist, and appears to selectively use references and data. IARC cites detections of glyphosate in different matrices (urine, serum, soil, air, water, and food) without putting the levels and potential exposures into the proper context. Regulatory authorities and JMPR establish ADIs and/or AOELs which account for potential human exposures and which establish safe exposure levels. When exposure is put into context it is consistently clear that there are no health concerns with 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 conclusion 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 from the largest and most important study into the health of pesticide applicators (The Agricultural Health Study) in the US which found no link between glyphosate and non-Hodgkin's lymphoma or any another cancer.

IARC classifies substances on the basis of their non-standard cancer hazard identification process. Apart from glyphosate, over the years IARC classified many other substances, professions, foods, and objects of every-day use to varying degrees of "evidence" for carcinogenicity. IARC's classifications are not based on the potential overall cancer hazard indicated by all cancer-related studies, but can be the result of one or more studies in which there is a statistically significant difference between control and one or more treated groups. Weight of evidence from the full set of studies and exposure are not at all taken into account. Therefore, IARC's 2A classification of glyphosate does not reflect a comprehensive look on carcinogenicity hazard, and does not present a thorough exposure or risk assessment.

IARC is only one of four programs within the WHO that have reviewed the safety of glyphosate, and the IARC classification is inconsistent with the assessments of the other programs. Two of the WHO programs (the Core Assessment Group of JMPR and the International Programme on Chemical Safety) previously concluded glyphosate is not carcinogenic. WHO Guidelines for Drinking-Water Quality concluded glyphosate does not represent a hazard to human health.

In closing, I would reiterate that Regulatory authorities around the world agree that there is no evidence that glyphosate causes cancer, even at very high doses, and that it is not genotoxic. I strongly disagree with OEHHA's intention to list glyphosate under Prop 65.

Sincerely,