

Message

From: JENKINS, DANIEL J [AG/1920] [REDACTED]
Sent: 6/24/2015 1:32:17 PM
To: HEYDENS, WILLIAM F [AG/1000] [REDACTED]
CC: LISTELLO, JENNIFER J [AG/1000] [REDACTED]
Subject: RE: GA Update on US Government Outreach - WHO IARC Clarification on Glyphosate

Completely agree. Mary Manibusan told me yesterday that EPA has had several issues in the past with ATSDR coming to different conclusions. She said they tried to execute several MOUs but were unsuccessful. She describes ATSDR as being VERY conservative and IARC like in this regard as well as the fact that they are hazard based.

Makes me very nervous, but I asked Jack whether or not he was worried about ATSDR coming out with something different and he said he wasn't and I think he was being genuine.

Dan Jenkins
U.S. Agency Lead
Regulatory Affairs
Monsanto Company
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Suite 450 East
Washington, DC 20005

[REDACTED]
[REDACTED]

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Wednesday, June 24, 2015 8:49 AM
To: JENKINS, DANIEL J [AG/1920]
Cc: LISTELLO, JENNIFER J [AG/1000]
Subject: RE: GA Update on US Government Outreach - WHO IARC Clarification on Glyphosate

Dan,

'Distinguishable and not duplicative'? Seriously? And I will believe the not 'making a call on cancer' part when I see it.

Anyway, at least they know they are being watched, and hopefully that keeps them from doing anything too stupid...

Thanks much for the follow-up.

Bill

From: JENKINS, DANIEL J [AG/1920]

Sent: Tuesday, June 23, 2015 8:17 AM

To: DYKES, MICHAEL D [AG/1920]

Cc: VAUGHN, TY T [AG/1000]; JACOBS, ERIK [AG/1000]; REYNOLDS, TRACEY L [AG/1000]; MARTINO-CATT, SUSAN J [AG/1000]; STATER, STACEY L [AG/1000]; DUNCAN, MELISSA S [AG/1000]; SCHLICHER, MARTHA A [AG/1000]; PARRISH, MICHAEL [AG/1000]; CHRISTIANSEN, JESSICA [AG/1000]; LISTELLO, JENNIFER J [AG/1000]; MILLER, PHILIP W [AG/1000]; AGUSTIN, MELISSA [AG/1920]; GUARD, JAMES [AG/1000]; HORAK, MICHAEL J [AG/1000]; COLE, RICHARD M [AG/1000]; HEERING, DAVID C [AG/1000]; REBMAN, JOHN [AG/1000]; TRAVIS, JAMES K [AG/1920]; FARMER, DONNA R [AG/1000]; LOWRY, BRIAN R [AG/1000]; KUSCHMIDER, SCOTT [AG/1920]; MURPHY, STEPHANIE L [AG/1920]; HOLLAND, MIKE [AG/1920]; HEYDENS, WILLIAM F [AG/1000]

Subject: RE: GA Update on US Government Outreach - WHO IARC Clarification on Glyphosate

Spoke to EPA:

ATSDR Director and Branch Chief have promised Jack Housenger (Director of the US Office of Pesticide Programs) to put their report "on hold" until after EPA releases its preliminary risk assessment (PRA) for glyphosate. EPA will not have the final meeting of its internal cancer review technical group until after the IARC monographs are published, and thus will not put out the PRA until after this (guessing this would mean around mid-August).

ATSDR has cited a GAO Audit report in arguing that their process is distinguishable and not duplicative. They look at different endpoints and told EPA they don't "make a call on cancer", but I think we should continue to be cautious.

EPA will send me the name of the Branch Chief so that we can hopefully set up a meeting.

Thanks,

Dan Jenkins
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[REDACTED]

From: DYKES, MICHAEL D [AG/1920]

Sent: Sunday, June 21, 2015 11:44 PM

To: JENKINS, DANIEL J [AG/1920]

Cc: VAUGHN, TY T [AG/1000]; JACOBS, ERIK [AG/1000]; REYNOLDS, TRACEY L [AG/1000]; MARTINO-CATT, SUSAN J [AG/1000]; STATER, STACEY L [AG/1000]; DUNCAN, MELISSA S [AG/1000]; SCHLICHER, MARTHA A [AG/1000]; PARRISH, MICHAEL [AG/1000]; CHRISTIANSEN, JESSICA [AG/1000]; LISTELLO, JENNIFER J [AG/1000]; MILLER, PHILIP W [AG/1000]; AGUSTIN, MELISSA [AG/1920]; GUARD, JAMES [AG/1000]; HORAK, MICHAEL J [AG/1000]; COLE, RICHARD M [AG/1000]; HEERING, DAVID C [AG/1000]; REBMAN, JOHN [AG/1000]; TRAVIS, JAMES K [AG/1920]; FARMER, DONNA R [AG/1000]; LOWRY, BRIAN R [AG/1000]; KUSCHMIDER, SCOTT [AG/1920]; MURPHY, STEPHANIE L [AG/1920]; HOLLAND, MIKE [AG/1920]; HEYDENS, WILLIAM F [AG/1000]

Subject: Re: GA Update on US Government Outreach - WHO IARC Clarification on Glyphosate

The person I talked with at HHS said they had checked with ATSDR and confirmed their review of glyphosate. I explained that their review was duplicative and I was now concerned about another glyphosate review coming any day. He said he didn't know when but didn't expect anything out of ATSDR for at least two weeks and suggested that we should meet with the technical people at ATSDR to better understand their process and timing.

I assume you have already met with the ATSDR people. I suggest you follow up with them just to confirm the facts as you may already know them as that will be more accurate than the information I received from HHS

You now have all the information I received from my conversation with HHS

Michael

Sent from my iPhone

On Jun 21, 2015, at 6:15 PM, JENKINS, DANIEL J [AG/1920] <[REDACTED]> wrote:

Michael:

Can you clarify what you're referring to regarding reports from ATSDR? They're not scheduled to put anything out for public comment until October- has this been accelerated?

Dan Jenkins

US Agency Lead

Monsanto Company

[REDACTED]

[REDACTED]

On Jun 19, 2015, at 4:10 PM, DYKES, MICHAEL D [AG/1920] <[REDACTED]> wrote:

REPORT ON FOLLOW UP DISCUSSION WITH HHS ON REQUEST FOR WHO CLARIFICATION

After repeated attempts, I connected this morning with Mitch Wolfe, Deputy Assistant Secretary for Global Affairs at HHS. I connected with one of his colleagues last week as a follow-up to our June 5 meeting but there was nothing significant to report.

Mitch reports that they have been assessing the collective actions across the USG on glyphosate. They have an interagency call today to discuss our request for a clarification from the WHO to ask if the other agencies are aligned. He plans to have more information available next week. He does not expect to have a final conclusion coming out of today's meeting. I reminded him that the final monograph is expected to be released on July 15 and the urgency of our request.

I then asked for an update on ATSDR. He said that they had checked with ATSDR and they were in fact doing a glyphosate review. I explained that this confirmed what we already understood but our question was about the purpose and scope of such a duplicative review by ATSDR. I also told him that we were concerned that ATSDR may come out any day with a report. He said that he thought it would be at least 2 weeks before they issued any reports. I again stressed that we were concerned that they were even reviewing glyphosate as were the people we talked with at EPA. He suggested that we should reach out to the reviewers at ATSDR. He is sending me the most appropriate contact point at ATSDR.

We also received intelligence today that ATSDR has reached out to other companies that sell glyphosate asking questions about glyphosate. If we have not already met with the technical people at ATSDR to understand their scope of investigation and timing of their report, I suggest that we meet with ATSDR as soon as something can be scheduled. HHS confirmed today that they are preparing a report.

CONGRESSIONAL SUPPORT SOUGHT FOR HHS ACTION

While we work to secure a commitment from HHS to obtain a clarification from the WHO, we are also focusing members of congress to engage HHS leadership to support this effort.

In particular, we have briefed the senior staff of our home state senators Roy Blunt (R-MO) and Claire McCaskill (D-MO) with the goal of those senators sending a letter to Ambassador Jimmy Kolker, the Assistant Secretary of Global Health at HHS, that underscores the urgent need for a WHO clarification with a direct ask that HHS do so.

In addition to representing our headquarters, Senator Blunt is also the Chairman of the Senate Appropriations Subcommittee that has oversight of HHS. Given his familiarity with the agency, his request would likely compel HHS leadership to make a thoughtful evaluation.

In addition, we have briefed key Senate Agriculture Committee staff should we need additional input from the Senate.

Lastly, we are also capitalizing on an opportunity in the House of Representatives. Last week, HHS Secretary Sylvia Burwell testified before the House Ways & Means Committee about the Administration's view on the current health care law, an issue which has come to the forefront in advance of an anticipated ruling by the Supreme Court in late June. While the hearing was focused on health care, members of the committee have the ability to submit *Questions for the Record*, or QFR's to the Secretary on any subject after the hearing has concluded. The Secretary is compelled to respond to those questions in writing.

The value of submitting a statement and question through this process is that it forces an agency to pull in expertise from its various departments because it is a deliberative effort that becomes part of the Congressional Record.

Representative Lynn Jenkins has agreed to submit a statement to HHS Secretary Burwell this week. The QFR will underscore the domestic and international confusion that has been generated and squarely asks the Secretary to seek a much needed clarification from the WHO.

From: DYKES, MICHAEL D [AG/1920]

Sent: Friday, June 05, 2015 3:59 PM

To: VAUGHN, TY T [AG/1000]; JACOBS, ERIK [AG/1000]; REYNOLDS, TRACEY L [AG/1000]; MARTINO-CATT, SUSAN J [AG/1000]; STATER, STACEY L [AG/1000]; DUNCAN, MELISSA S [AG/1000]; SCHLICHER, MARTHA A [AG/1000]; PARRISH, MICHAEL [AG/1000]; CHRISTIANSEN, JESSICA [AG/1000]; JENKINS, DANIEL J [AG/1920]; LISTELLO, JENNIFER J [AG/1000]; MILLER, PHILIP W [AG/1000]; AGUSTIN, MELISSA [AG/1920]; GUARD, JAMES [AG/1000]; HORAK, MICHAEL J [AG/1000]; COLE, RICHARD M [AG/1000]

Cc: TRAVIS, JAMES K [AG/1920]; FARMER, DONNA R [AG/1000]; LOWRY, BRIAN R [AG/1000]; KUSCHMIDER, SCOTT [AG/1920]; MURPHY, STEPHANIE L [AG/1920]; HOLLAND, MIKE [AG/1920]

Subject: US Government Outreach - WHO IARC Clarification on Glyphosate

This message provides an update on Washington based efforts to assist Monsanto teams managing the IARC issue.

THE STRATEGY

One strategy for addressing widespread confusion in the wake of the IARC classification has been to seek clarification from the World Health Organization (WHO) which would provide the proper context of the classification for governments and regulators around the world to have greater confidence defending their science based regulatory decisions. Because IARC is part of

the WHO, the clarification would be a compelling tool for governments and stakeholders to reference.

RECENT ACTIONS

To execute against this strategy, the Washington office has conducted significant outreach within the U.S. government to secure its engagement with the WHO in an effort to obtain that clarification.

We have briefed key staff at EPA, USTR, USDA and the State Department as well as members of Congress. These officials are interested in clarifying this issue for several reasons: maintaining scientific integrity that promotes public confidence, protect international trade and the economy and preserve safe, valuable tools for farmers continued use.

HEALTH & HUMAN SERVICES: A KEY AGENCY BRIEFED

Yesterday, we briefed officials at Health and Human Service (HHS), the agency that will be particularly crucial because it is the primary U.S. government interlocutor with the WHO. Its support will be key to the U.S. government effort to secure a WHO clarification.

Specifically, we met with Dr. Mitchell Wolfe, the Deputy Assistant Secretary for Global Health. Donna Farmer traveled to Washington to help with the briefing. Her knowledge and background with glyphosate was instrumental in communicating information to the Secretary, who himself is a medical doctor.

We came prepared with a robust set of technical materials for the Secretary's background. In addition, we were joined by a small group of value chain stakeholders to underscore the challenges the confusion of the IARC classification and concomitant media reports have generated in a short period of time. Those groups included the American Farm Bureau Federation, the National Corn Growers Association and the U.S. Grains Council.

The HHS briefing covered the following:

- Overview of the concerns raised by IARC's classification: health concerns, undermining national and international regulatory authorities reviews, food security and impact on agricultural trade (bans and restrictions).
- We described the reviews and toxicological profile of glyphosate - multiple reviews that have been conducted by agencies around the world, whose primary responsibility is to assess the safety of pesticides, and that over 40 years those agencies have repeatedly come to the conclusions that glyphosate is not carcinogenic or genotoxic and that it does not pose a carcinogenic risk to humans.
- We discussed that the strikingly different conclusion that IARC came to was not based on new data but the way IARC reviews existing data. For example an increase in tumors in low-dose animals compared to controls with no increase in the numbers of tumors in higher doses is considered as evidence of cancer in animals – thus a “created hazard”. In addition a timeline of international responses to the IARC classification over the past several months including impacts on regulatory reviews not only for glyphosate but biotech products, bans and proposed bans on uses and suspensions of imports was provided;
- Dr. Wolfe was not aware that the Agency for Toxic Substances and Disease Registry (ATSDR, an agency under HHS) is currently doing a review of glyphosate as well as 2,4-D. It was discussed that similar to IARC, this is not the primary role of this agency – the US EPA is the primary agency for review and determination of pesticide safety and that glyphosate is currently undergoing registration review by the EPA.
- A common element between IARC and ATSDR was brought to Dr. Wolfe's attention; Christopher Portier, Ph.D. Dr. Portier was Director of ATSDR and the co-chair of the IARC Advisory Group that met in April of 2014 to recommend priorities for IARC Monographs during 2015-2019. He was also an invited specialist representing the Environmental Defense Fund at IARC's meeting when glyphosate was reviewed in March 2015. Dr. Wolfe said he would follow up on what was going on with ATSDR and he was encouraged to have discussions with EPA staff, as well.
- Next, the farm groups articulated how challenges surrounding the IARC classification were negatively impacting their members and the potential for even greater challenges should a clarification not be made. They highlighted the need for tools like glyphosate and maintaining trade that is so critical to America's farm economy. The farm organizations added significant value to the discussion.
- Finally, we ended the discussion with the request for HHS assistance in securing a WHO clarification. We emphasized that we were not seeking changes to IARC, the classification or the IARC process. Dr. Wolfe commented that he felt that this was a reasonable request and

indicated that he was in Geneva when the Lancet article came out in March and that he had been expecting to hear from us. Dr. Wolfe and his staff will review the material and delve deeper on a number of the areas of discussion. We will follow up with HHS.

NEXT STEPS

In the coming week, we will follow up with all of the previously briefed U.S. agencies and seek requests to the Administration from key members of Congress outlining the need for a WHO clarification and urge that they secure it before the release of the IARC monograph on glyphosate anticipated in July.

Donna Farmer, Jim Travis , Brian Lowry & Michael Dykes