

Message

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Sent: 6/5/2015 9:38:06 PM
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Subject: Fwd: US Government Outreach - WHO IARC Clarification on Glyphosate

FYI

Sent from my iPhone

Begin forwarded message:

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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

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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:

- <!--[if !supportLists]--><!--[endif]-->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).
- <!--[if !supportLists]--><!--[endif]-->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.
- <!--[if !supportLists]--><!--[endif]-->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;
- <!--[if !supportLists]--><!--[endif]-->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.
- <!--[if !supportLists]--><!--[endif]-->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.
- <!--[if !supportLists]--><!--[endif]-->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.

- <!--[if !supportLists]--><!--[endif]-->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