

Glyphosate: IARC

INTRODUCTION

The International Agency for Research on Cancer (IARC), part of the World Health Organization, coordinates and conducts both epidemiological and laboratory research into the causes of human cancer. It also evaluates the carcinogenic potential of individual substances based only on publicly available information. While glyphosate has been a low priority for evaluation by IARC for more than two decades, it was nominated for review in mid-April, 2014.

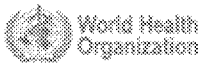
After learning of the ~~nomination~~ selection of glyphosate for review in September, the regulatory team's initial focus was publishing safety studies that were not yet in the public domain. All research had to be published or accepted for publication by Feb. 3, 2015 to be considered in the IARC review. Regulatory Affairs has shared these recent publications with IARC and is continuing to share directly with panelists and observers.

IARC has a history of questionable and politically charged rulings on the carcinogenic properties of products such as cell phones, coffee and caffeine. We should assume and prepare for the outcome of a 2B rating (*possible* human carcinogen); a 2A rating (*probable* human carcinogen) is possible but less likely.

It is possible that IARC's decision will impact future regulatory decision making. Regulatory is not aware of a situation where a regulatory body took a different position than IARC. Competent authorities for regulating pesticides and assessing chemical hazard typically evaluate a broader range of studies and make their own decisions. They also use the most broadly accepted hazard classification system, the Globally Harmonized System, which differs significantly from that used by IARC. Thus IARC classifications can readily differ from those of other regulatory bodies. This could further delay the U.S. EPA review.

The IARC meeting where glyphosate will be reviewed and the decision will be made will occur March 3-10, 2015. IARC will post its decision soon after on its website ({ HYPERLINK "http://www.iarc.fr" }). We are already seeing activists increase allegations against the Roundup brand (ilo glyphosate) and link those allegations directly to GM crops. We anticipate this will increase with the IARC decision. CLI seems to be willing to develop high-level communications around the IARC process to prepare for the publication of the IARC decision. To date, CLA and ECPA have not been engaged; we will need industry support specific to the glyphosate rating.

International Agency for Research on Cancer



"The International Agency for Research on Cancer (IARC) is the specialized cancer agency of the World Health Organization"

TEAM

Jen Listello	Reg Affairs – US	LEAD
Kelly Claus	Issues Preparedness and Engagement	
Linda Dudenhoeffer	Stakeholder Outreach	
[REDACTED]	Regulatory Affairs – Global	
Bill Heydens	Regulatory Product Safety Assessment / Strategy	
Dan Jenkins	U.S. Agency Regulatory Affairs	
Kim Link	Issues Preparedness and Engagement	
Kim Magin	Industry Affairs	
John Vicini	Regulatory Policy / Scientific Affairs	

Comment [wh1]: No – contact with panelists ('Members') is not allowed

Comment [wh2]: And key regulators

Formatted: Complex Script Font: +Body (Calibri), 10 pt, Highlight

Comment [wh3]: No GHS doesn't play into this. I would say "more broadly accepted 'Weight-of-Evidence' approach to evaluate carcinogenic potential, which..."

Comment [k4]: and EU? Canada? Japan?

Comment [drf5]: We asked CLA to nominate an observer to the meeting. while they were supportive there was push back by some of the member companies that this action would supporting a "single ai" we tried to make the case that this is about defending pesticides but that argument didn't work with those companies

Glyphosate: IARC				
KEY DELIVERABLES				
Due Date	Who/What	Objective	MON Owner	Status
Pre-Decision/Posting				
Feb 3, 2015	Deadline for data submission	Update public record with most current and complete data	Bill Heydens	Complete
	Monsanto.com/glyphosate	Update to include gly not carcinogen	Bill Reeves Kyel Richard	
Week of Feb. 23-27				
Planning and Preparation				
	Engage Henry Miller	Inoculate / establish public perspective on IARC and reviews	Eric Sachs	
	Blog post to reiterating gly not carcinogen/tweets	Establish SM content and amplify scientific studies	Aimee Hood Kim Link Heather McClurg	
	Outreach to EPA / IARC participants	Ensure awareness of scientific studies	Dan Jenkins	
Prior to March 3	Contact journals to inquire about press releases for 6 new publications	Amplification of scientific studies	David Saltmiras	
	Inform/ Engage Industry Associations	Lead voice in "who is IARC" plus 2B outrage	Kim Link Kelly Clauss [REDACTED] Kim Magin	Ongoing
	Engage CLI and regional industry associations in communications	Communicate the perspective of the IARC process	Kelly Clauss [REDACTED]	Ongoing
	Address new allegations	Neutralize impact	Kim Link Charla Lord	Ongoing
	Outreach to / collaboration with DAS (2,4D scheduled for IARC review in June 2015)	Maximize efforts / coordinated industry response	Bill Heydens Donna Farmer	Ongoing
	Global Reg Affairs (Canada, US, EU, LAS, Brazil, Asia Pacific, India)	Inform ongoing activities for regulator outreach	[REDACTED]	Ongoing
Week of March 2-6				
Implement Inoculation Plan / Continue Preparations				
	Engage with experts to plan for publications and other activities in case IARC classification is unfavourable	Respond to the classification and defend at global regulatory	Bill Heydens, Donna Farmer John Acquavella	

Comment [drf6]: [HYPERLINK "http://www.monsanto.com/glyphosate/documents/no-evidence-of-carcinogenicity.pdf"]; [HYPERLINK "http://www.monsanto.com/glyphosate/pages/is-glyphosate-safe.aspx"] we already have statements and a backgrounder out there that says just that – is this something different?

Glyphosate: IARC				
		authorities		
	Share SM messages (Twitter, Facebook)	Amplify positive gly content	Kim Link Heather McClurg	
	Prepare key Monsanto spokespeople	Ensure strong, consistent MON messaging	FH Kelly Clauss	
	Communicate to employees via ET email and Connection article	Raise awareness and inoculate employees	Jaclyn Pollnow	
Post-Decision/Posting				
Week of March 9-13	Implementation of Crisis Plan, as necessary			
March 10	Outreach to key stakeholders (utilize discussion guide)	Neutralize impact of decision / gain active support	Linda Dudenhoeffer	
March 10	Outreach to grower groups (utilize discussion guide, provide key talking points)	Neutralize impact of decision / gain active support	Kim Magin IA colleagues	
	Outreach to regional regulators	Neutralize impact of decision / gain active support	Dan Jenkins Regional RA	
@ Posting	Publish / amplify blog post on the meaning of the IARC ruling	Ensure MON POV / neutralize SM	Kim Link Charla Lord Heather McClurg	
@ Posting	Add IARC statement to web	Ensure MON POV / neutralize SM	Kyel Richard	
@ Posting	Publish Connection article for employees	Ensure MON POV	Jaclyn Pollnow	
@ Posting	Outreach to ag media	Ensure MON POV in coverage	John Combest	
See Attachment A: Communications Plan				
RESOURCES				
EXTERNAL (Glyphosate is not carcinogenic)				
<ul style="list-style-type: none"> • @EPA concluded in 2013 that "glyphosate does not pose a cancer risk to humans" [HYPERLINK "http://www.regulations.gov" \ "documentDetail;D=EPA-HQ-OPP-2012-0132-0009"] • @EPA groups glyphosate in the lowest category E, indicating glyphosate does not pose a cancer risk to humans http://www.epa.gov/oppsrrd1/reregistration/REDs/factsheets/0178fact.pdf • FAQ #7 Does glyphosate cause cancer? [HYPERLINK "http://www.monsanto.com/glyphosate/pages/glyphosate-frequently-asked-questions.aspx" \ "seven"] • Backgrounder Glyphosate: No evidence of carcinogenicity [HYPERLINK "http://www.monsanto.com/glyphosate/Documents/no-evidence-of-carcinogenicity.pdf"] • Discover.com [HYPERLINK "http://discover.monsanto.com/conversation/question/are-you-ready-to-be-held-accountable-for-the-many-diseases-which-are-caused-by-your-poison-such-as-leaky-gut-syndrome-and-cancer"] 				

Comment [k7]: Ensure Mink link is fixed

Glyphosate: IARC

- GMOAnswers, Does glyphosate cause cancer? [HYPERLINK "<http://gmoanswers.com/ask/does-glyphosate-cause-cancer>"]
- GMOAnswers, Breast cancer from glyphosate? [HYPERLINK "<http://gmoanswers.com/ask/how-can-you-say-they-are-safe-when-recent-studies-not-conducted-monsanto-show-direct-link-breast>"]
- Science Direct, Epidemiologic studies of glyphosate and non-cancer health outcomes: [HYPERLINK "<http://www.sciencedirect.com/science/article/pii/S0273230011001516>"]
- Regul Toxicol Pharmacol. Epidemiologic studies of glyphosate and cancer: a review.
 - <http://www.ncbi.nlm.nih.gov/pubmed/22683395>

INTERNAL

- xxx

Formatted: Font: (Default) +Body (Calibri), Complex Script Font: +Body (Calibri), 10 pt

Formatted: Font: (Default) +Body (Calibri), Complex Script Font: +Body (Calibri), 10 pt

Comment [drf8]: If this is about cancer why is the Mink non-cancer health out comes here and not the cancer review?

Formatted: Font: (Default) +Body (Calibri), Complex Script Font: +Body (Calibri), 10 pt

Formatted: Normal, Indent: Before: 0.5", No bullets or numbering

Draft Feb 23, 2015

**ATTACHMENT A: PREPAREDNESS AND ENGAGEMENT PLAN
FOR IARC CARCINOGEN RATING OF GLYPHOSATE**

Last Updated: February 17, 2015

OBJECTIVES FOR PREPAREDNESS & ENGAGEMENT

- Protect the reputation and FTO of Roundup by communicating the safety of glyphosate
- Amplify science-based information to prevent unfounded claims from becoming popular opinion
- Provide cover for regulatory agencies to continue making re-registration decisions based on science

AUDIENCES

- IARC Panelists and Observers
- Regulators
- Stakeholders
- Farmer Customers

STRATEGIES/TACTICS

PRE-IARC

1. Amplification of Scientific Studies

- Support the development of three new papers on glyphosate focused on epidemiology and toxicology
- Work with RPSA and Strategic Communications to amplify existing studies and new papers
 - Authors work directly with scientific journals to issue alerts and news releases on new bodies of work
 - RPSA posts blog from first-person viewpoint of Monsanto's David Saltmiras, co-author of one of the glyphosate cancer papers
 - Share resources and content with Monsanto key regions to amplify the message globally

2. Inform / Inoculate / Engage Industry Partners

- Develop a "toolkit" containing key information and resources
 - Identify any message shortcomings and address through updates to monsanto.com/glyphosate and through US and EU blog posts
- Work with RPSA, Stakeholder Outreach Team, Industry Affairs, Government Affairs, US Business, Global CE and Regulatory teams, etc. to engage industry partners
 - Tier 1: Crop Life International / European Crop Protection Association / GMO Answers / BIO – identify committees that are best to engage
 - Tier 2: Academics (AgBioChatter), Biofortified, Sense About Science, Genetic Literacy Project, Academics Review
 - Tier 3: Alert food companies via Stakeholder Engagement team (IFIC, GMA, CFI) for "inoculation strategy" to provide early education on glyphosate residue levels, describe science-based studies versus agenda-driven hypotheses
 - Tier 4: Inoculate key grower associations

3. Address New Allegations

- Respond quickly and publically to new pseudoscience cancer studies
- Identify / request third-party experts to blog, op/ed, tweet and/or link, repost, retweet, etc.

POST-IARC

4. Orchestrate Outcry with IARC Decision ~ March 10, 2015

- Industry conducts robust media / social media outreach on process and outcome
 - [Sense About Science?] leads industry response and provides platform for IARC observers and industry spokesperson
 - CLI and other associations issue press releases

Draft Feb 23, 2015

- Joint Glyphosate Taskforce publishes press release, letter signed by leaders of each manufacturer in North America and Europe
- Push opinion leader letter to key daily newspaper on day of IARC ruling with assistance of Potomac Group
- Monsanto responds with strong reactive statement
 - Distribute video and audio responses to IARC decision
 - Address media inquiries with company glyphosate spokesperson
 - Utilize Monsanto channels (web, FB, Twitter, blog, etc) to provide Monsanto POV
 - Corporate Engagement team packages industry and Monsanto responses, then distributes via email to ~20 most influential ag media outlets across print, radio and TV

5. Engage Regulatory Agencies

- Grower associations / growers write regulators with an appeal that they remain focused on the science, not the politically charged decision by IARC