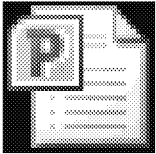


Message

From: HEYDENS, WILLIAM F [AG/1000] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=230737]
on behalf of HEYDENS, WILLIAM F [AG/1000]
Sent: 5/11/2015 12:43:25 PM
To: KOCH, MICHAEL S [AG/1000] [/O=Monsanto/OU=NA-1000-01/cn=Recipients/cn=MSKOCH]; FARMER, DONNA R [AG/1000] [/o=Monsanto/ou=NA-1000-01/cn=Recipients/cn=180070]; HODGE-BELL, KIMBERLY C [AG/1000] [/O=Monsanto/OU=NA-1000-01/cn=Recipients/cn=KCHODG]; SALTMIRAS, DAVID A [AG/1000] [/O=Monsanto/OU=NA-1000-01/cn=Recipients/cn=DASALT]
Subject: RE: Post-IARC Activities to Support Glyphosate
Attachments: Post-IARC Meeting Science Proposals.pptx

All,

See attached, which reflects the results of conversations Donna & I had with various stakeholders (e.g., Law, CE, RPSA). This will be the basis of our discussion today. Thanks.



-----Original Appointment-----

From: KOCH, MICHAEL S [AG/1000]
Sent: Friday, May 08, 2015 11:07 AM
To: KOCH, MICHAEL S [AG/1000]; HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; SALTMIRAS, DAVID A [AG/1000]
Subject: Post-IARC Activities to Support Glyphosate
When: Monday, May 11, 2015 1:00 PM-2:00 PM (UTC-06:00) Central Time (US & Canada).
Where: Grow Room in D Building

A couple of you will need to leave at 1:50 to make a 2:00 pm meeting in C on Monday. This will be a weekly meeting; they were to be re-occurring but because everyone's calendar is almost full, I will probably have to make them separate days and times each week.

Chris on behalf of Mike Koch

Proposal for Post-IARC Meeting Scientific Projects

DRAFT

May 11, 2015

Why do more?

- Severe stigma attached to Group 2A Classification
- Aaron Blair continues to defend work & exaggerate number of studies w/ association while ignoring AHS
- In response to our critique, can expect IARC to beef-up monograph as much as possible
- IARC plans to pool data globally in the future
 - Blair announced at meeting that he has already put together an unofficial work group to begin the process
 - North American Pooled Project (NAPP) already underway and early results reported in 2014
 - Believe this will be used to move pesticides to Group 1
- Provide additional support ('air cover') for future regulatory reviews
 - Broad EU review recently recommended by BfR
 - Other regulatory agencies stated they will review after Monograph publishes
- ASTDR evaluation
- 
- Litigation support

Counter IARC's selective use of data and flawed analyses/conclusions on Epidemiology, Animal Bioassays, and Genotoxicity (Mode of Action); Prevent future adverse outcomes

Possibilities:

- Conduct and Publish new Meta-analysis
- Publication on Animal Data Cited by IARC**New*
- Publish updated AHS study data
- Publish WoE/Plausibility Paper
- Genetox/MOA

New Meta-analysis

- **Project Description**

- Conduct proper meta-analysis to support the position that glyphosate is NOT associated with NHL and multiple myeloma
- Publish separately & can be used in overall WOE/Plausibility publication (below)
- Could be completed/published prior to IARC Monograph

- **Risk**

- None, since we have already done the analysis

- **Cost**

- \$32K plus any translation costs

[Timing – Donna checking w/ Exponent, but currently estimate 3-4 months to write plus 2+ months to get online publication]

Publication on Animal Carcinogenicity Data

- **Project Description**

- Publication on Animal Data Noted by IARC as Evidence for Carcinogenicity
- Studies/Tumors Involved:
 - Mouse kidney tumors – subject of claims that Monsanto convinced EPA to change conclusions
 - Haemangiosarcoma in mice (Cheminova), pancreatic islet cell tumors in 2 rat studies (Monsanto) – multiple regulatory reviews conducted, including WHO/FAO
 - Publication on Initiation-promotion study with Roundup®
- Greim & 1or 2 other external authors?
- Could be completed/published prior to IARC Monograph
- Could we add Japan data (TAC, Mitsui (formerly Sankyo)? Would likely increase timeline

- **Cost**

- Majority of writing can be done by Monsanto, keeping OS\$ down

AHS Collaboration

- **Project Description**

- Submit proposal to AHS to collaborate on project to add last several 10 years of data & publish
- Do with expert academicians – (e.g., Tom Sorahan, Tim Lash, David Coggin)

- **Risk – low**

- We already know data is ‘negative’ through 2008/2009 (Freeman *et al*, 2009)
- AHS certainly would have already published any “+”
- Write stringent protocol ahead of time
- ‘Seasoned’ rational experts would be doing the analysis not just post-docs from AHS who need to ‘make a mark’

- **Downside**

- Longer term project – won’t get quick results
- AHS Executive Committee may decline
 - Plan B -> FOI Request

- **Cost**

- Total ~\$75K; initial cost to make proposal substantially less

Overall WOE/Plausibility Publication Possibly via Expert Panel Concept

- **Project Description**
 - Publish comprehensive evaluation of carcinogenic potential by credible scientists
- **Possible Panelists/Authors**
 - Solomon? (Exposure), Sorahan (Epidemiology), Greim? (Animal bioassay), G. Williams, Kirkland? (Genetox/MOA), Sir Colin Barry, Jerry Rice (ex-IARC head)
- **Cost**
 - \$200 – 250 K, depending on:
 - Who/how many scientists we include
 - How much writing can be done by Monsanto scientists to help keep costs down
 - Alternative: 1 or 2 separate publications w/ subset of authors?

Genetox / MOA

- Counter IARC's claim of strong evidence of DNA damage/oxidative stress
- Could be important for future litigation support
- Gary Williams (NY Medical College) - Use gene expression to firm-up non-genotoxic MOA in positive *in vitro* studies with formulations
- Contact Rich Irons?

Feedback

Conduct and Publish new Meta-analysis

- **Legal** – value not apparent
- **RPSA** – ‘No-Brainer’
- **CE** – Makes sense; have pre-release and/or present at scientific meeting before publication; RPSA needs to work on explaining to public
- **Brussels RA** – clear value; get out before IARC Monograph

Publish updated AHS study data

- **Legal** – most appealing; MON somewhat distanced & AHS involved
- **RPSA** – ‘No Brainer’; add 2,4-D & dicamba?
- **CE** – Makes sense; have pre-release and/or present at scientific meeting before publication; RPSA needs to work on explaining to public
- **Brussels RA** – clear value; agree w/ RPSA; get out before IARCMonograph if possible (not likely)

Feedback

Publish WoE/Plausibility Paper

- **Legal** – Appealing; best if use big names; better if sponsored by some group
- **RPSA** – How helpful to regulators? Could we do totally independent?
- **CE** - If done, real value in having 3rd party manage process; add a couple MDs; work with Shawna to have a couple key stakeholders (e.g., GMA) watch/hear the proceedings & take back to their communities
- **Brussels RA** – less clear benefit; will it really ‘trump’ IARC in needed circles?

Genetox/MOA

- **Legal** – cannot assess value
- **RPSA** – Need to address this; include household surfactants
- **CE** – no real comment
- **Brussels RA** – agree with RPSA; also finish Nik Hodges study

Additional Suggestions from CE

- Get someone like Jerry Rice (ex-IARC) to publish paper on IARC
 - How it was formed, how it works, hasn't evolved over time, they are archaic and not needed now
- Exposure paper that shows how exposure is really, really low!
- Form Crop Protection Advisory Group?
 - Includes nutritionist, MDs along with traditional science groups; include a NGO?
 - Internal contacts = Mike Parish/ Matt Helms, Kelly Fleming, C Vance Crow, Janice Persons
- Communication Plans
 - Need to build in right plans for all steps/actions, including plan that works for millennials; start as early as possible