

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.

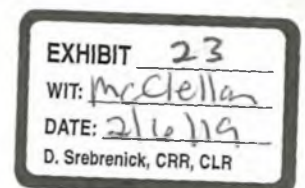


-----Original Appointment-----

**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
- Prop 65
- 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 & 1 or 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 3<sup>rd</sup> 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, Cvance Crow, Janice Persons
- Communication Plans
  - Need to build in right plans for all steps/actions, including plan that works for millenials; start as early as possible