

Proposal for Post-IARC Meeting Scientific Projects

DRAFT

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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 & 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, 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