Hi Khue:

We made some minor corrections in the notes, please see the attached version.

Also, per EPA's request at the 4/6/16 meeting, see attached tox study bibliography which represents the overwhelming majority of studies on glyphosate and glyphosate formulations. Later this week, we anticipate providing a list of additional studies that were done on final formulations as well as the a.i., that BfR (the EU rapporteur) did not review because they were only submitted in non-EU countries.

Regarding EPA's formulation questions in your prior email, and as discussed in the meeting on 4/6/16, our answer is below:

For the glyphosate epidemiology studies noted by EPA, the results were published in the scientific literature during the 2001 – 2009 timeframe; data capture for these studies would have terminated a few years prior to the publication dates (factoring in time to organize/analyze results, perform statistics, write the publications, complete the peer-review process, etc.). Thus, the exposures to the applicators in these studies that are most relevant likely occurred in the 1990s and 1980s. The surfactant system used almost exclusively in Roundup agricultural herbicide formulations globally throughout these two decades contained a polyethoxylated tallow amine surfactant (some phosphate ester surfactant usage began in the late 1990s). Rather, differences in study size and experimental design/analysis (e.g., consideration of potential exposure and controlling for bias/confounding factors) are considered to be responsible for the apparent differing results.^{*1,2}

*1: Final Addendum to the renewal assessment report on glyphosate, compiled by EFSA, October 2015.

http://registerofquestions.efsa.europa.eu/rogFrontend/outputLoader?output=ON-4302



Request to consider the findings by IARC as regards the potential
carcinogenicity of glyphosate or glyphosate containing plant protection
products in the ongoing peer

*2: EFSA explains the carcinogenicity assessment of glyphosate:

http://www.efsa.europa.eu/sites/default/files/4302_glyphosate_complementary.pdf

Thanks and please let us know if you have any questions.

Best Regards,

Dan Jenkins U.S. Agency Lead

Regulatory Affairs Monsanto Company 1300 I St., NW Suite 450 East Washington, DC 20005

Office: 202-383-2851

Cell: 571-732-6575

From: Nguyen, Khue [mailto:Nguyen.Khue@epa.gov]
Sent: Wednesday, April 06, 2016 2:57 PM
To: JENKINS, DANIEL J [AG/1920]; LISTELLO, JENNIFER J [AG/1000]; HEERING, DAVID C [AG/1000]; HEYDENS, WILLIAM F [AG/1000]; NYANGULU, JAMES M [AG/1920]
Cc: Anderson, Neil; Moriarty, Thomas; Smith, Charles; Lowit, Anna; Perron, Monique; Dunbar, Anwar; Bloem, Thomas
Subject: notes from April 5 glyphosate meeting

Hi all,