From: ianpanton@aol.com [mailto:ianpanton@aol.com]
Sent: Monday, September 19, 2016 2:10 AM
Subject: Glyphosate:FIFRA Scientific Advisory Panel:EPA-HQ-OPP-2016-0385/EPA-HQ-OPP-2016-0385-0001

Open Letter

Steve Knott
EPA

19 September 2016

Dear Mr Knott,

FIFRA Scientific Advisory Panel on Glyphosate:EPA-HQ-OPP-2016-0385/EPA-HQ-OPP-2016-0385-0001

I recently had occasion to view:

https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0001

Glyphosate Issue Paper: Evaluation of Carcinogenic Potential EPA's Office of Pesticide Programs September 12, 2016, of which I attach a copy.

I especially noted that:

"Recently, EPA collected and analyzed a substantial amount of data informing the carcinogenic potential of glyphosate and utilized its draft "Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment" to assess the potential carcinogenic hazard. The draft framework provides the foundation for evaluating multiple lines of scientific evidence and includes two key components: Problem formulation and use of the mode of action/adverse outcome pathway (MOA/AOP) frameworks. A comprehensive analysis of data on glyphosate from submitted guideline studies and the open literature was performed. This includes epidemiological, animal carcinogenicity, genotoxicity, metabolism, and mechanistic studies. Guideline studies were collected for consideration from the toxicological databases for glyphosate and glyphosate salts. A fit-for-purpose systematic review was executed to obtain relevant and appropriate open literature studies with the potential to inform the human carcinogenic potential of glyphosate. Furthermore, the list of studies obtained from the toxicological databases and systematic review was cross-referenced with recent internal reviews, review articles from the open literature, and international agency evaluations (i.e., IARC, EFSA, JMPR).

Available data from epidemiological, animal carcinogenicity, and genotoxicity studies were reviewed and evaluated for study quality and results to inform the human carcinogenic potential of glyphosate. Additionally, as described in the draft "Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment,"

the multiple lines of evidence were integrated in a weight-of-evidence analysis using the modified Bradford Hill Criteria considering concepts, such as strength, consistency, dose response, temporal concordance, and biological plausibility. The agency will solicit advice from the SAP on the evaluation and interpretation of the available data for each line of evidence and the weight-of-evidence analysis, as well as how the available data inform cancer classification descriptors according to the agency's 2005 Guidelines for Carcinogen Risk Assessment"

mention of:

Effect on Cellular Processes
Benachour, N. and G.-E. Seralini (2009). "Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells." Chem Res Toxicol 22(1): 97-105.

and:

Page 176
Not Relevant to current fit for purpose review
Mesnage, R., et al. (2013). "Ethoxylated adjuvants of glyphosate-based herbicides are active principles of human cell toxicity." Toxicology 313(2-3): 122-128.

However, vide the statement at page 186:

Retracted Article
Séralini, G.-E., et al. (2014). "Retraction notice to “Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize” [Food Chem. Toxicol. 50 (2012) 4221–4231]." Food and Chemical Toxicology 63: 244.

and mention at page 158 of:

Correspondence article
Wallace Hayes, A. (2014). "Editor in Chief of Food and Chemical Toxicology answers questions on retraction." Food and Chemical Toxicology 65: 394-395.

I would respectively point out that the subject paper was in fact republished and hence remains extant.

I attach a copy for your further information and trust the EPA will ensure this unfortunate oversight is immediately addressed.

Kind Regards

Ian Panton