EXHIBIT 24

Docket Number EPA-HQ-OPP-2009-0361
www.regulations.gov

Glyphosate

Proposed Interim Registration Review Decision
Case Number 0178

April 2019

Approved by: _____

Charles "Billy" Smith
Acting Director
Pesticide Re-evaluation Division

Date: 4/23/19

Table of Contents

concentration, a 10 kg child would have to consumer approximately 385 liters of orange juice every day to reach the chronic reference dose of 1 mg/kg/day (the maximum acceptable oral dose that is the threshold of concern).

EPA evaluated dietary exposure to all population subgroups, including children, infants, and women of child-bearing age. There were no dietary risks of concern for glyphosate using an unrefined analysis, which (1) assumes that all food commodities contain maximum legal residues (*i.e.*, tolerance-level residues) and all registered food crops have been treated with glyphosate, and (2) uses high-end estimates of glyphosate in drinking water.

Commenters point to the use of glyphosate as a pre-harvest desiccant for wheat as a source of glyphosate residues in cereal products. The wheat desiccant use was considered in the agency's dietary risk assessment; EPA assumed maximum legal residues in wheat and other cereal grains. Taking exposures from those residues into consideration in its most recent human health risk assessment, EPA's estimation of risk from aggregate exposure to glyphosate, even including residues from pre-harvest desiccant use on wheat, is below the agency's level of concern. However, the agency has received a petition from the Environmental Working Group concerning the tolerance for oats and pre-harvest use on oats for which the agency is taking public comment. Additional information is described in section I.B of this document.

Comments on Formulations Toxicity:

Many commenters expressed concerns that glyphosate formulations are more toxic than glyphosate alone and questioned the toxicity of inert ingredients and the lack of transparency for inert ingredients and other contaminants in pesticide products.

The EPA Response: Most pesticide products contain substances in addition to the active ingredient (known as inert ingredients) which aid in the performance and effectiveness of the pesticide product. All active and inert ingredients must be approved by the agency when a pesticide product is first registered, including for glyphosate products. Since there are over 500 glyphosate products registered at different times in the US, the agency has assessed new inert ingredients at multiple points over the years for different formulations of glyphosate. The EPA evaluates the active and inert ingredients' hazard potential (*i.e.*, toxicity) with a battery of toxicity data. Any contaminants or impurities associated with formulation components must be reported to the agency and evaluated on a case-by-case basis. The agency reviews the amount in the formulation, the manufacturing information, and information on what steps are taken to limit or remove impurities. EPA can require that any inert ingredients of toxicological concern be listed in the ingredients statement of the label if determined to pose a hazard to humans or the environment (CFR § 156.10(g)(7)).

Glyphosate has been studied in a multitude of studies, including on multiple formulations that contain glyphosate. All studies of adequate scientific caliber that the Agency was aware of were incorporated into the risk assessment. For the glyphosate ecological risk assessment, ecotoxicity data on glyphosate formulations were reviewed in addition to data on glyphosate alone and relevant studies were summarized in the *Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and its Salts*.

For human health risk assessment, the EPA searched the open literature to find glyphosate formulations toxicity data but there are few research projects that have attempted to directly compare technical grade glyphosate to the formulations under the same experimental design. Furthermore, there are even fewer instances of studies comparing toxicity across formulations. Most studies using commercial formulations identified as part of EPA's review were *in vitro* studies, which are difficult to translate into *in vivo* effects where metabolism and clearance would play a large role in potential toxicity. EPA gave *in vivo* studies greater weight, however none of the *in vivo* studies with commercial formulations were found to be of adequate quality for use in human risk assessment. Common limitations observed in *in vivo* formulations studies include: lack of test material information, exposure conditions not adequately described/documented, data were presented only as graphs and measures of variability were not included, samples sizes were too small or not reported, only one dose was tested, age/health of study animals were not reported, and a mode of action/adverse outcome pathway was not established.

The EPA has been collaborating with the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences to develop research intended to evaluate the role of glyphosate in product formulations and the differences in formulation toxicity. The results of this research will be considered when available. Additional information on the NTP research plan for glyphosate is available online: https://ntp.niehs.nih.gov/results/areas/glyphosate/index.html.

If at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, the EPA intends to review it and determine the appropriate regulatory action.

Comments About the Monarch Butterfly:

Many commenters such as the Center for Food Safety, Center for Biological Diversity, Natural Resource Defense Council, and Beyond Pesticides expressed concerns that the EPA's risk assessment is not protective of monarch butterflies and plant resources for monarchs, such as milkweed. In general, commenters asserted that the EPA has not done enough to protect monarch butterflies when monarch populations have been in decline in recent decades. Commenters urged the EPA to restrict or ban glyphosate on the grounds that it is killing milkweed, a key resource for monarch butterfly larvae.

The EPA Response: Monarch butterfly conservation is an important issue for the agency. While herbicides like glyphosate have been implicated in the decline of the monarch butterfly population, it is not known to what extent pesticides in general may play a role. It is important to note that threats to the monarch butterfly population are multi-pronged and include loss of breeding habitat, loss of overwintering habitat in Mexico,[2] changes in weather patterns (including winter storms), disease, and other factors.[3]

[2] Vidal, O., Lopez-Garcia, J., and Rendon-Salinas, E. (2014), Trends in Deforestation and Forest Degradation after a Decade of Monitoring in the Monarch Butterfly Biosphere Reserve in Mexico. *Conservation Biology*, 28: 177-186.
[3] Agrawal, A. and Inamine, H. (2018), Mechanisms behind the monarch's decline. *Science*, 22: vol. 360, Issue 6395, pp.1294-1296.