



October 28, 2019

Environmental Working Group Comments to the Environmental Protection Agency

Docket ID: EPA-HQ-OPP-2011-0855

Subject: Registration review draft human health risk assessment for paraquat dichloride

Environmental Working Group, a nonprofit research and policy organization with offices in Washington, D.C., Minneapolis, San Francisco and Sacramento, Calif., is submitting comments on the Environmental Protection Agency's draft human health risk assessment for the pesticide paraquat dichloride, commonly called paraquat.

EWG has researched pesticide toxicity since 1993, bringing public attention to the risks of pesticides to children's health. EWG is particularly concerned about paraquat toxicity and the long-term health harm that paraquat exposure can pose both to the general public and to agricultural workers.

The EPA currently allows both agricultural and non-agricultural uses of paraquat; it can be used for pre-planting and post-emergence applications, as well as a desiccant/harvest aid and a postharvest desiccant. As the EPA has stated, paraquat spraying can lead to contamination of drinking water sources. In sum, people may be exposed to paraquat from both food and water, in addition to occupational and bystander exposure from paraquat spraying.

EWG has identified several critical flaws in the EPA's draft human health risk assessment, specifically in the agency's assessment of paraquat toxicity. To remedy these flaws, EWG urges the EPA to revise the paraquat human risk assessment in three key areas:

1. Recognize and address the neurotoxic effects associated with paraquat.
2. Include the 10X Food Quality Protection Act children's health safety factor in paraquat assessment.
3. Establish strict limits for paraquat to protect children's health and the health of agricultural workers.

Details about these recommendations are presented below.

1. Address the neurotoxic effects associated with paraquat

The EPA's draft human health risk assessment incorrectly focuses on just one aspect of paraquat's toxicity, namely, the harm that this pesticide causes to lungs and respiratory health. Although the respiratory toxicity of paraquat is well established, the EPA's overall approach



entirely misses the importance of paraquat's neurotoxicity. An extensive body of research has established that paraquat can kill dopaminergic neurons and cause neurodegenerative changes.¹

In its draft human health risk assessment, the EPA's chronic reference dose for paraquat exposure is based on two studies of paraquat toxicity in dogs. These studies were conducted by the Chevron Chemical Company in 1981 and 1983 and neither has been published in peer-reviewed research literature. Those studies are now more than 35 years old and cannot be considered adequate for the assessment of paraquat's long-term effects on the human nervous system. Moreover, the EPA has failed to require paraquat manufacturers to conduct a developmental neurotoxicity study for this chemical.

The EPA's draft assessment already lists some animal studies that identify the neurotoxic effects of paraquat; however, it did not use those studies for the development of the chronic reference dose. To address this gap, EWG urges the EPA to use the neurotoxicity information as the point of departure for the reference dose.

2. Include the 10X Food Quality Protection Act children's health safety factor

In the draft human health risk assessment for paraquat, the EPA presented its rationale for reducing the Food Quality Protection Act, or FQPA, Safety Factor to 1X for all exposure scenarios relevant to children by asserting that “the toxicity database, with contributions from the open literature, is adequate to evaluate the potential for susceptibility in infants and young children resulting from exposure to paraquat” and that “the [Points of Departure] are protective of all known health effects resulting from paraquat exposure including evidence of susceptibility and neurotoxicity in the open literature.”

EWG strongly disagrees with the EPA's statement that the points of departure chosen for the draft assessment for paraquat are “protective of all known health effects.” As summarized in section 1 above, the EPA's approach used studies on dogs from the 1980s and fails to adequately consider the risk of neurotoxicity. Moreover, EPA's own assessment finds that “limited evidence of age-related sensitivity [to paraquat] was observed in the open literature...” (section 4.4 of the draft human health risk assessment, “Safety Factor for Infants and Children”). These effects are particularly significant for exposure to paraquat in combination with other contaminants, such as the fungicide maneb.²

¹ Reviewed in Zhang XF, Thompson M, Xu YH. 2016. Multifactorial theory applied to the neurotoxicity of paraquat and paraquat-induced mechanisms of developing Parkinson's disease. *Lab Invest.* 96(5): 496-507. doi: 10.1038/labinvest.2015.161.

² Li B, He X, Sun Y, Li B. 2016. Developmental exposure to paraquat and maneb can impair cognition, learning and memory in Sprague-Dawley rats. *Mol Biosyst.* 12(10):3088-97. doi: 10.1039/c6mb00284f; Colle D, Farina M, Ceccatelli S, Raciti M. 2018. Paraquat and Maneb Exposure Alters Rat Neural Stem Cell Proliferation by



EPA dismissed the findings of age-related sensitivity to paraquat, stating that these effects are applicable only to “*exposure to a high purity paraquat product (>98% purity), which is not representative of the lower purity technical paraquat products and formulations (<48% purity) undergoing Registration Review.*” EWG disagrees with the agency’s rationale and finds that the above statement is inconsistent with the basic principles of toxicology. If a high-purity material is associated with a particular type of toxicity, this indicates that the above-referenced toxicity represents the feature of the compound itself. Therefore, if age-related neurodevelopmental sensitivity from exposure to high purity paraquat was observed, the same effects would be reasonably expected for all preparations of paraquat.

In sum, because of the risk of harm to children’s health, and concern about paraquat’s developmental neurotoxicity, a 10X children’s health safety factor should be used for paraquat human health risk assessment.

3. Establish strict limits on paraquat use in the U.S.

EWG is very concerned that the EPA’s plan to allow continued paraquat use poses significant risk to human health and the environment. As the data in the U.S. Geological Survey database show, paraquat use has been on the rise in the U.S., from around 4 million pounds annually, in 2010-2013, to more than 8 million pounds, in 2016, the latest data year currently available on the USGS website.³

The EPA’s draft assessment found that children one to two years old are the most highly exposed population subgroup for paraquat in the U.S. Once the appropriate 10X FQPA Children’s Health Safety Factor is included in the risk assessment, we can conclude that infants and all children up to age 12 are likely exposed to paraquat from food and drink in amounts that exceed the level of concern. This conclusion points to the stark public health risks associated with the current use of paraquat in this country. Thus, EWG urges the EPA to establish strict limits on paraquat use and set up much stricter tolerance levels for the residual levels of paraquat in foods in order to protect the health of the general public, especially children, and the health of agricultural workers who are exposed to this dangerous chemical on the job.

Submitted on behalf of the Environmental Working Group,

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Inducing Oxidative Stress: New Insights on Pesticide-Induced Neurodevelopmental Toxicity. *Neurotox Res.* 34(4):820-833. doi: 10.1007/s12640-018-9916-0.

³ USGS. Pesticide National Synthesis Project. Pesticide Use Maps – Paraquat. Available at https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2016&map=PARAQUAT&hilo=L&di sp=Paraquat Accessed October 23, 2019.