January 10, 2020

Environmental Working Group Comments to the Environmental Protection Agency
Docket ID: EPA-HQ-OPP-2018-0094
Subject: Children's health safety assessment for tebuconazole

The Environmental Working Group, a nonprofit research and policy organization with offices in Washington, D.C., Minneapolis, Minn., San Francisco and Sacramento, Calif., submits comments on the Environmental Protection Agency's human health risk assessment for the fungicide tebuconazole. EWG has researched pesticide toxicity since 1993, bringing public attention to the risks of pesticides to infants and children. In order to protect children's health, EWG urges the EPA to apply a full tenfold FQPA safety factor for tebuconazole, in place of the threefold FQPA factor that the EPA chose.

The toxicity of tebuconazole to developing organisms is documented in the EPA's own assessment of this fungicide. In animal studies, exposure to tebuconazole caused malformations in nervous system development, changes in brain morphometric parameters, and decreases in motor activity.[1] Peer-reviewed studies have reported that tebuconazole alters testosterone production[2] and testicular morphometry.[3] Further, the EPA classifies tebuconazole as a "possible human carcinogen." The European Union classifies tebuconazole as "suspected of damaging the unborn child," and a 2014 review by the European Food Safety Agency suggested that the chemical be classified as one that "may damage the unborn child."[4]

The adverse effects associated with tebuconazole exposure, and the evidence of pre- and postnatal toxicity, warrant the application of a full tenfold FQPA safety factor for all routes of exposure to tebuconazole. In fact, a tenfold FQPA safety factor for tebuconazole was proposed in 1998, when EPA scientists first reviewed the potential impacts of this pesticide on children's health and wrote that the developmental effects observed in animal studies were "quite severe."[5]

In its 2019 assessment, the EPA used a developmental neurotoxicity study in rats for the development of both the acute and chronic reference doses for tebuconazole exposure. In that study, offspring experienced toxicity effects at the lowest dose tested (8.8 mg/kg/day), and no "No Observed Adverse Effects Level" dose was identified. The dose of 8.8 mg/kg/day cannot be considered a lowest adverse effect level; rather, it is just the

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lowest dose tested in the study submitted by the pesticide manufacturer. The true "Lowest Observed Adverse Effect Level", or LOAEL, might be significantly lower. This absence of a defined LOAEL is another compelling reason why a tenfold FQPA children's health safety factor should be applied to tebuconazole.

Infants and children 1 to 2 years old already face the highest exposure to tebuconazole from food and drinking water of all humans, according to the EPA's assessment, published in 2008.[6] In fact, data from the most recent round of fruit and vegetable testing as part of the Pesticide Data Program indicate tebuconazole was detected on more than 60 percent of raisins, a common children's health food snack.[7] The EPA's proposed increase in tolerances, the allowable maximum limits of tebuconazole on foods, could double the total exposure to tebuconazole, and for some age groups, the exposure would be more than two times higher.[8]

In summary, given the health risks associated with tebuconazole, the EPA's proposed increase in tebuconazole use is of great public health concern. EWG urges the EPA not to increase allowable tolerances for tebuconazole on foods, and instead to take measures that would limit the exposure of infants and children to this pesticide.

Submitted on behalf of the Environmental Working Group,

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[1] Environmental Protection Agency. Tebuconazole 7E8648 - HED Signed HH Risk Assessment October 18, 2019; Tebuconazole 7E8648 - HED Signed Acute-Chronic Risk Assessment October 16, 2019. https://www.regulations.gov/docket?D=EPA-HQ-OPP-2018-0094

[2] Chen X, Zhu Q, Li X, Huang T, Wang S, Wang Y, Chen X, Lin Z, Ge RS. Pubertal exposure to tebuconazole increases testosterone production via inhibiting testicular aromatase activity in rats. Chemosphere 2019; 230: 519-526. https://doi.org/10.1016/j.chemosphere.2019.05.122

[3] Machado-Neves M, Neto MJO, Miranda DC, Souza ACF, Castro MM, Sertorio MN, Carvalho TF, Matta SLP, Freitas MB. Dietary exposure to tebuconazole affects testicular and epididymal histomorphometry in

frugivorous bats. Bull Environ Contam Toxicol. 2018; 101(2): 197-204. https://doi.org/10.1007/s00128-018-2377-6

[4] European Food Safety Authority (EFSA). Conclusion on the peer review of the pesticide risk assessment of the active substance tebuconazole. EFSA Journal 2014; 12(1): 3485. https://www.efsa.europa.eu/en/efsajournal/pub/3485

[5] Environmental Protection Agency. Tebuconazole - Report of the FQPA Safety Factor Committee. Tox review 012534. 1998. https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/html/128997.html

[6] U.S. Environmental Protection Agency. Tebuconazole: Human Health Risk Assessment to support tolerances in/on Asparagus, Barley, Beans, Beets, Brassica Leafy greens, Bulb Vegetables, Coffee (import), Commercial Ornamentals, Corn, Cotton, Cucurbits, Hops, Lychee, Mango, Okra, Pome Fruit, Soybean, Stone fruit, Sunflower, Tree Nut Crop Group, Turf, Turnips and Wheat. 2008. https://www.regulations.gov/document?D=EPA-HQ-OPP-2005-0097-0004

[7] U.S. Department of Agriculture (USDA). Pesticide Data Program Databases and Annual Summaries. 2018 Annual Pesticide Data Program Summary. https://www.ams.usda.gov/datasets/pdp/pdpdata

[8] Environmental Protection Agency. Tebuconazole; Pesticide Tolerances. 2019. https://www.regulations.gov/docket?D=EPA-HQ-OPP-2018-0094