

October 16, 2024

Office of Pesticide Programs Environmental Protection Agency, (28221T) 1200 Pennsylvania Ave., NW Washington, DC 20460-0001

Re: Pesticide Registration Review: Proposed Decisions for Several Pesticides [EPA-HQ-OPP-2015-0291-0087, EPA-HQ-OPP-2009-0317-0171]

Dear Madam/Sir,

These comments are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers, and farmworkers. Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

For the Environmental Protection Agency's (EPA) proposed interim decisions regarding the pesticide registration reviews of malathion and mancozeb, Beyond Pesticides advocates for EPA to carry out its statutory responsibility under the *Federal Insecticide Fungicide and Rodenticide Act* (FIFRA) to protect human and environmental health from the unreasonable impacts of these pesticides and revoke any associated uses. Studies find both malathion, an organophosphate insecticide, and mancozeb, an ethylene bisdithiocarbamate (EBDC) fungicide, to be neurotoxic and potentially carcinogenic to humans, as well as toxic to many other organisms.

Malathion has been linked to cancer, endocrine disruption, reproductive effects, neurotoxicity, kidney/liver damage, skin irritation, and birth/developmental effects. Impacts on the environment are also noted, as this pesticide leaches and is detected in groundwater. While malathion is toxic to humans, it is also toxic to birds, fish, and bees. According to EPA, numerous fish kills resulting from malathion use followed by heavy rainfall and runoff into aquatic areas, such as streams and ponds, have occurred. Impacts of the environment are also noted, as this pesticide leaches and is detected in groundwater.

Malathion, like all other organophosphate insecticides, works to kill insects by inhibiting important enzymes of the nervous system, specifically acetylcholinesterase (AChE). As a nerve poison, this correlates with the cases of long-lasting polyneuropathy and sensory damage that have been reported in humans, as well as behavioral changes.^{3,4} Additionally, DNA damage has

¹ Beyond Pesticides, Gateway on Pesticide Hazards and Safe Pest Management for Malathion: https://www.beyondpesticides.org/resources/pesticide-gateway?chemfind=malathion

² U.S. EPA. 2016. "Biological Evaluation Chapters for Malathion ESA Assessment." Available at https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion-esa-assessment

³ Petty, C. 1958. "Organic phosphate insecticide poisoning." American Journal of Medicine 24:467-470.

⁴ Harell, et al. 1978. "Bilateral sudden deafness following combines insecticide poisoning." Larynogoscope 88:1348.

Beyond Pesticides EPA-HQ-OPP-2009-0317-0171 EPA-HQ-OPP-2015-0291-0087

been linked to frequent contact with malathion, and cell studies reveal cytotoxic and genotoxic effects.^{5,6}

Research finds that exposure to organophosphates, like malathion, correlate with neurological health problems including Parkinson's disease. This is not surprising, as organophosphates are known to be extremely toxic to nerve cells and fatal at high doses. There is also research into long-term effects, including a 2012 meta-analysis that found that long-term, low-dose exposure to organophosphates can damage neurological and cognitive functions. Additional studies link malathion, and mancozeb, to mental health effects leading to depression in suicide, particularly in exposed farmers.

The primary metabolite of malathion, malaoxon, also poses a health risk. As malathion degrades in the environment into malaoxon, additional toxicity needs to be considered. In the 2016 human health assessment for malathion, EPA evaluated the ratio of toxicity between malathion and malaoxon and found that malaoxon is 22 times more toxic than malathion.¹⁰

With organophosphates' common mechanism of toxicity and aggregate exposures from food, water, and pesticide drift from applications, coupled with their low-level potency, the agency must act with urgency to formally revoke all registrations and uses of this class of pesticide, starting with malathion. EPA's assessment of residential and occupational exposures from malathion shows that there are risks of concern that cannot be ignored, and given the legacy of organophosphates, all uses must finally be phased out. EPA has identified several risks of concern related to malathion use, which cannot be ignored or successfully mitigated. Dermal and inhalation exposures continue to pose the most risks from residential and occupational uses. Spray drift, which is inevitable given the current allowable uses of malathion, also raises concern.

Malathion and other organophosphates, with their pervasive exposures and unreasonable neurotoxic impacts, among others, carry too high a risk for continued use. 11,12 It is paramount that the public's health is safeguarded from unnecessary exposures to such neurotoxins. Beyond Pesticides objects to the use of neurotoxic agents to combat mosquito populations, given the availability of ecological approaches and the scientific understanding and documentation of insect resistance.

⁵ Herath, J. F., Jalal, S. M., Ebertz, M. J., & Martsolf, J. T. (1989). Genotoxicity of the organophosphorus insecticide malathion based on human lymphocytes in culture. *Cytologia*, 54(1), 191-195.

⁶ Moore PD, Yedjou CG, Tchounwou PB. 2010. Malathion-induced oxidative stress, cytotoxicity, and genotoxicity in human liver carcinoma (HepG2) cells. *Environ Toxicol*. 25(3):221-6.

⁷ Pezzoli, G., & Cereda, E. (2013). Exposure to pesticides or solvents and risk of Parkinson disease. *Neurology*, 80(22), 2035-2041.

⁸ Ross, S. M., McManus, I. C., Harrison, V., & Mason, O. 2013. Neurobehavioral problems following low-level exposure to organophosphate pesticides: a systematic and meta-analytic review. *Critical reviews in toxicology*, 43(1), 21-44.

⁹ Zheng, R. et al. (2024) Depressive symptoms and suicide attempts among farmers exposed to pesticides, *Environmental Toxicology and Pharmacology*. Available at:

https://www.sciencedirect.com/science/article/pii/S1382668924001017?via%3Dihub.

¹⁰ USEPA. 2016. Malathion: Human Health Draft Risks Assessment for Registration Review. Office of Chemical Safety and Pollution Prevention. Washington DC.

¹¹ Rauh VA, Perera FP, Horton MK, et al. 2012. Brain anomalies in children exposed prenatally to a common organophosphate pesticide. *Proc Natl Acad Sci USA*. 109(20):7871-6.

¹² Morgan, M.K., Wilson, N.K. and Chuang, J.C. (2014) Exposures of 129 Preschool Children to Organochlorines, Organophosphates, Pyrethroids, and Acid Herbicides at Their Homes and Daycares in North Carolina, *International Journal of Environmental Research and Public Health*. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4025031/.

The authors of a study on resistance conclude, "Our in situ and laboratory condition experiments show that populations of the mosquito *Ae. aegypti*, present in the analysed areas, are resistant to malathion." They continue, "[W]e suggest it is important to consider the susceptibility of the vector as a strategic component, a key part of integrated action to reduce vector populations in urban areas." This is especially important in light of current concerns regarding mosquito-borne diseases and escalating problems with pesticide efficacy. Ecological pest management is safer and more efficacious. The risks to the public are too high, and we urge EPA to move forward with the cancellation of malathion uses.

The pesticide of concern, mancozeb, has been linked to cancer, endocrine disruption, skin irritation, reproductive effects, and birth/developmental effects in humans in addition to being toxic to fish and bees. ¹⁴ As a contact fungicide, mancozeb reacts with amino acids and enzymes of fungi on the leaves of the plant in which it is applied.

Exposure to mancozeb, regarding endocrine disruption, has been linked particularly to thyroid toxicity and thyroid tumors. The European Food Safety Authority reports that mancozeb is a full endocrine-disrupting pesticide, is classified as toxic to reproduction, and poses high risks to aquatic organisms, birds, mammals, non-target arthropods, and soil macroorganisms, among others. Additional studies connect mancozeb to Parkinson's disease, as well as respiratory, hepatic, renal, and genotoxic effects. Additional studies connect mancozeb to Parkinson's disease, as well as respiratory, hepatic, renal, and genotoxic effects.

Although pesticides are by definition harmful, what makes these adverse effects "unreasonable" is not only the elevated harm associated with the chemical but the existence of an alternative—an organic production system—that does not harm human health, other species, or ecosystems. Additionally, the organic approach helps to mitigate climate change, and issue that the agency is charged with considering in its decision making. ¹⁹ In all its decisions, EPA must use organic production as a yardstick, denying any toxic chemical for which organic production is successful.

EPA is required to consider these alternative management practices and materials that are available, such as those used in organic agriculture, to make an accurate assessment, compliant with the unreasonable adverse effects standard of FIFRA,²⁰ of the hazards associated with continued and expanded pesticide use.

¹³ de Souza Leandro, A. (2020) Malathion insecticide resistance in *Aedes aegypti*: laboratory conditions and in situ experimental approach through adult entomological surveillance, *Tropical Medicine & International Health*. Available at: https://onlinelibrary.wiley.com/doi/10.1111/tmi.13474.

¹⁴ Beyond Pesticides, Gateway on Pesticide Hazards and Safe Pest Management for Mancozeb: https://www.beyondpesticides.org/resources/pesticide-gateway?pesticideid=206

¹⁵ Pesticide Action Network Europe, Mancozeb Factsheet. Available at: https://www.pan-europe.info/sites/pan-europe.info/sites/pan-europe.info/files/public/resources/briefings/Factsheet%20Mancozeb%20-%20March%202020.pdf

¹⁶ Peer review of the pesticide risk assessment of the active substance mancozeb (2020) *European Food Safety Authority (EFSA) Journal*. Available at: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.5755.

¹⁷ Pouchieu, C. et al. (2017) Pesticide use in agriculture and Parkinson's disease in the AGRICAN cohort study, *International Journal of Epidemiology*. Available at: https://academic.oup.com/ije/article/47/1/299/4609336.

¹⁸ Dall'Agnol, J. (2021) Systemic effects of the pesticide mancozeb - A literature review, *European Review for Medical and Pharmacological Sciences*. Available at: https://pubmed.ncbi.nlm.nih.gov/34156691/.

¹⁹ Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, January 20, 2021. Available at: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/

²⁰ Federal Insecticide, Fungicide, and Rodenticide Act 7 U.S.C. §136 et seq. (1996).

We urge the agency to revoke the registration of these compounds due to findings of high risk and demonstrated adverse impacts. We reiterate our appeal that the agency adheres to FIFRA's statutory mandate and immediately suspends the registration of both malathion and mancozeb that pose unreasonable and adverse health and environmental effects.

Thank you for your consideration of our comments.

Respectfully,

Sara Grantham

Science, Regulatory, and Advocacy Manager