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March 27, 2017

OPP Docket
Docket Center (EPA/DC), (28221T
U.S. Environmental Protection Agency Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001

Re: Pesticide Experimental Use Permits, Malathion. Docket No.: EPA-HQ-OPP-2016-0628

Dear Madam/Sir,

We are writing to oppose the request for the experimental use permit (EUP) for malathion, which is aimed at generating mosquito data for new malathion formulations. FMC Corporation submitted an application (279-EUP-U), and the U.S. Environmental Protection Agency (EPA) reasons that the permit may have regional and national significance. However, we believe malathion, a neurotoxic organophosphate pesticide, should not be allowed for mosquito control based on documented risks to human and environmental health. An EUP granted for field application of malathion for mosquito control will serve to further endanger human and environmental health. Strategies to control mosquito populations, in light of new and emerging diseases, must consist of more holistic and sustainable approaches that involve reducing mosquito breeding sites, surveillance, public education, and the judicious use of least-toxic larvicides. As a result, the use of highly hazardous agents like malathion is unnecessary given risks to public health, increasing mosquito resistance, and the general lack of efficacy of adulticiding.

According to EPA, manufacturers are required to obtain an EUP before testing "new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water."[1] Further, 40 C.F.R. 172.11(a) states that EPA must publish a notice in the Federal Register of the application for an EUP when EPA finds that issuance of the EUP may be of regional and national significance. The notice shall include:

(1) The active ingredients,
(2) Use pattern(s),
(3) Quantity of pesticide,
(4) Total acreage,
(5) Location of area of application,

[1] https://www.epa.gov/pesticide-registration/types-registrations-under-fifra.

(6) A statement soliciting comments from any interested persons regarding the application.[2]

However, the notice published to the Federal Register does not include the prescribed information, especially the total acreage to be treated for the EUP, and is therefore incomplete.[3]

As an organophosphate insecticide, malathion is a cholinesterase inhibitor that is associated with neurological impairments. The scientific database is clear on the neurological risks associated with exposure to malathion and other organophosphates.[4,5,6] Malathion's use as a mosquito adulticide is problematic, given its potential impacts on communities and non-target organisms. Broadcast aerial and ground applications of the insecticide for mosquito control exposes the public, including vulnerable sub-populations like children, to a neurotoxic agent that has the potential to cause lasting neurological harms. EPA's recent preliminary assessment of malathion finds that there are risks of concern that cannot be ignored.[7] According to the assessment, there are dermal and inhalation exposure risks for adulticide applications. Risks were identified for post-application scenarios, including dermal, inhalation, hand-to-mouth, and object-to-mouth scenarios.[8] These risks are compounded by malathion spray drift[9] which can travel for miles, leading to inhalation and dermal exposures not sufficiently accounted for, affecting human and non-target organisms alike.

Malathion is classified by EPA as "suggestive evidence of carcinogenicity but not sufficient to assess human carcinogenic potential" by all routes of exposure. The International Agency for Research on Cancer (IARC) assessed the carcinogenicity of malathion in 2015 and classified it as "probably carcinogenic" to humans (Group 2A).[10] This is based on rodent studies in which malathion caused tumor development, as well as limited evidence from exposure studies for non-Hodgkin lymphoma and prostate cancer. Malathion is rapidly absorbed through the gastrointestinal tract, skin, and lungs and exhibits low acute toxicity through these routes.[11]

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[2] 40 C.F.R. 172.11(a).

[3] Federal Docket No.: EPA-HQ-OPP-2016-0628-0001.

[4] Androutsopoulos VP, Hernandez AF, Liesivuori J, Tsatsakis AM. 2013. A mechanistic overview of health associated effects of low levels of organochlorine and organophosphorous pesticides. Toxicology 307:89-94.

[5] Lee I, Eriksson P, Fredriksson A, et al. 2015. Developmental neurotoxic effects of two pesticides: Behavior and biomolecular studies on chlorpyrifos and carbaryl. Toxicol Appl Pharmacol. 288(3):429-38.

[6] Meijer M, Hamers T, Westerink RH. 2014. Acute disturbance of calcium homeostasis in PC12 cells as a novel mechanism of action for (sub)micromolar concentrations of organophosphate insecticides. Neurotoxicology. 43:110-6.

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

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

[9] Ibid.

[10] Fritschi, L., McLaughlin, J., Sergi, C. M., Calaf, G. M., Le Curieux, F., Forastiere, F., ... & Martin, M. T. (2015) Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. *Red*, *114*.

[11] U.S. EPA. 2009. Reregistration Eligibility Decision (RED) for Malathion. Office of Pesticides and Toxic Substances. Washington, DC.

One study finds malathion has genotoxic potential.[12] Another reports that malathion exposures induce cytotoxic and genotoxic effects in HepG(2) cells.[13]

Malathion is also hazardous to non-target organisms like honey bees.[14] Malathion sprayings have resulted in the death of many bees and impaired bee colonies due to application of malathion.[15] Previous studies have reported that colonies exposed to ultra-low volume (ULV) malathion weighed significantly less for up to 28 days when compared to control colonies, indicating colony decline.[16] Aquatic organisms including fish, invertebrates, and amphibians are also severely affected by malathion, as the insecticide is highly toxic to these organisms. According to EPA's registration documents for malathion, there are several toxicity studies with aquatic insect larvae which show that malathion is highly to very highly toxic to non-target insects with aquatic early life stages.[17]

Widespread adulticiding is not a solution for preventing or controlling mosquito populations and mosquito-borne diseases. There is already documented resistance among mosquito populations to malathion,[18,19] which will only continue to increase with further malathion use. Adulticiding with malathion fails to sufficiently control mosquito populations, promotes pesticide resistance, and kills other species that would have acted as a natural predator to mosquitoes.

The published notice does not provide pertinent information as to where, and how many acres on which malathion will be used. The public is thus under-informed on where and how widespread the application of these new malathion formulations will be, in violation of 40 C.F.R. 172.11(a). Further, new malathion formulations and uses are not options that are sustainable or effective for mosquito control. This EUP should not be granted since adulticiding with malathion poses risks to adults and children, as well as non-target organisms. In fact, EPA has identified several risks of concern related to malathion use that cannot be ignored or

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[12] Moore PD, Patlolla AK, Tchounwou PB. 2011. Cytogenetic evaluation of malathion-induced toxicity in Sprague-Dawley rats. *Mutat Res.*;725(1-2):78-82.

[13] 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.

[14] Aljedani, DM and Almehmadi, RM. 2016. Effects of some insecticides on longevity of the foragers honey bee worker of local honey bee race Apis mellifera jemenatica. *Electron Physician*. 8(1): 1843–1849.

[15] Sanford, M. Protecting Honey Bees From Pesticides. Circular 534. Florida Cooperative Extension Service, Institute of Food and Agricultural Sciences, University of Florida http://pollinatorstewardship.org/wp-content/uploads/2014/02/Protecting-Honey-Bees-Florida.pdf.

[16] Zhong H, Latham M, Hester PG, Frommer RL, Brock C. 2003. Impact of naled on honey bee Apis mellifera L. survival and productivity: aerial ULV application using a flat-fan nozzle system. *Arch Environ Contam Toxicol*. 45(2):216-20.

[17] USEPA. 2006. Reregistration Eligibility Decision (RED) for Malathion. Office of Pesticide Programs. Washington DC.

[18] Karunaratne, S. H. P. P., & Hemingway, J. 2001. Malathion resistance and prevalence of the malathion carboxylesterase mechanism in populations of mosquito vectors of disease in Sri Lanka. *Bulletin of the World Health Organization*, *79*(11), 1060-1064.

[19] Hidayati, H, Nazni, W.A., Lee, H.L and Sofian-Azirun, M. 2011. Insecticide resistance development in Aedes aegypti upon selection pressure with malathion. *Tropical Biomedicine* 28(2): 425-437.

successfully mitigated. Growing mosquito resistance to malathion further supports a denial of this EUP request. Therefore, we urge the agency to reject the application (279-EUP-U).

Thank you for your consideration of our comments.

Sincerely,

Nichelle Harriott
Science and Regulatory Director