



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 06 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dear Ms. Harriott and Mr. Feldman,

Thank you for your letter regarding the use of naled and pyrethroids in mosquito abatement programs to address the control of the Zika virus. Recognizing this imminent public health concern, the agency has been working with the Centers for Disease Control and Prevention (CDC) to provide the necessary information and assistance to different state, territorial, and local governments. This information will vary from one community to another due to differences in climate, housing, mosquito populations, etc. For example, in Puerto Rico, where Zika is quite prevalent, EPA has been working to promote the use of screens on windows and tire shredders to eliminate used tires as a source for mosquito breeding. While pesticides may help control mosquitos on a population basis, physical barriers are also an important tool for maintaining public health. An integrated vector management approach is important in curbing the spread of Zika and pesticide tools can be used as part of an overall comprehensive strategy. Your letter includes a variety of science, regulatory, and scheduling concerns which are addressed below.

Registration Review Schedule

The registration review process is intended to ensure that, as the ability to assess and reduce risks evolves and as policies and practices change, all registered pesticides continue to meet the statutory standards of no unreasonable adverse effects. The Preliminary Work Plan is the first step in the registration review process and the document includes the agency's knowledge about the pesticide, the anticipated risk assessment and data needs, and an **estimated** timeline for the review. As you are undoubtedly aware, the actual schedule for a chemical is often driven by the amount of time required for the anticipated and the unanticipated needs for each phase in the registration review process. Delays are generally the result of Data Call-In packages not being issued as anticipated due to delays in the review and approval by the Office of Management and Budget and changes to the timeframes for certain studies based upon lab availability or issues in conducting a study.

For naled and DDVP, the EPA's 2009 Final Work Plan estimated that the draft human health and ecological risk assessments would be completed by the end of 2013, and the final registration review decision would be completed by the end of 2015. The EPA is reviewing and assessing the potential risks associated with naled, trichlorfon, and DDVP together for consistency and efficiency. This approach is in line with the agency's workplan where we stated that the review would include DDVP, a degradate of naled and trichlorfon, as part of the total residues of concern. The assessments will also incorporate the agency's updated residential risk assessment and mosquito adulticide assessment methods. Specifically, the assessment will include updates to dietary, occupational and residential risk from all potential exposures to the three chemicals, and for all appropriate exposure routes (incidental oral, dermal and inhalation). All of the data that have been called in for registration review, which includes potential life

stage difference for cholinesterase effects, are undergoing internal reviews and the data reviews will be published in the public docket, along with the draft assessments when completed.

In addition to the chemical specific work being completed for naled, DDVP, and trichlorfon, the agency has also been evaluating additional data for organophosphate chemicals to determine if any additional regulatory changes are needed for these pesticides. In light of these efforts, the agency anticipates releasing the draft human health and ecological risk assessments for public comment in early 2017.

Similarly, for the two pyrethroids your letter mentions, both human health risk assessments for d-phenothrin (sumithrin) and permethrin are scheduled to be released for public comment in late 2016/early 2017. Both assessments will include the similar assessment updates previously mentioned. Additionally, in 2011 EPA completed a comprehensive human health cumulative risk assessment based upon a determination that pyrethroids, and the pyrethrins, share a common mechanism of action. The screening-level cumulative risk assessment was highly conservative, overestimating actual risk. The assessment assumed that people are exposed to the highest levels of residues in food, water, and in their homes, all on the same day. Even with these conservative and protective assumptions, the assessment shows that cumulative risks for both children and adults are not of concern for the pyrethrins/pyrethroid pesticides.

Assessment of Exposure to Naled and DDVP Resulting from Mosquito Adulticide Applications

Beyond Pesticides is correct that the 1999 naled assessment conducted during the reregistration process did not assess potential inhalation exposures to residential bystanders resulting from mosquito adulticide applications. At that time, it was not the EPA's policy to perform such an assessment, however, at the time the EPA did conduct an occupational handler inhalation assessment. Potential post-application bystander inhalation exposures, and therefore potential bystander inhalation risks, would be expected to be substantially less than those for handlers. This is due to the significant differences in application rates, level of exposure, and frequency of exposures.

Since 1999, the EPA has updated the residential risk assessment¹ methods as well as how risk is assessed for adults and children who may be exposed to pesticides from mosquito adulticide applications. The draft risk assessment that is underway will specifically include potential inhalation exposures to residential bystanders resulting from mosquito adulticide applications.

As noted in your letter, the EPA has recently completed an updated assessment for another mosquito adulticide, malathion². The malathion assessment incorporates the updated residential risk assessment and mosquito adulticide assessment methods mentioned previously. This includes the assessment of post-application inhalation bystander exposures. The naled and DDVP registration review risk assessments will assess potential exposures resulting from mosquito adulticide applications in a similar scope to the malathion document. Information on the malathion assessment, including an additional evaluation on how use of malathion can be modified to result in lower exposures and eliminate potential safety concerns, can be found on our website³.

¹ <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>

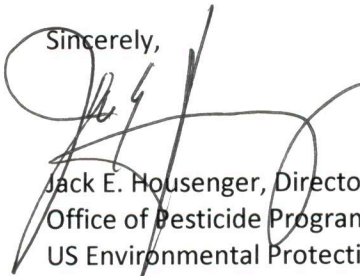
² <https://www.epa.gov/pesticides/epa-draft-malathion-human-health-assessment-available>

³ <https://www.epa.gov/mosquitocontrol/malathion>

European Union (EU) position on Naled

Your letter states that in 2012, the EU banned naled citing "potential and unacceptable risk" to human health and the environment. In Europe, naled has never been registered for aerial applications as a mosquito control product. During Europe's re-evaluation process in 2012, the registrant chose for business reasons not to support the continued registration of naled.

In summary, the EPA shares the public health concerns posed by Zika. The agency is actively engaged with state and local governments as well as the CDC to provide information and assistance to combat Zika. For the most up to date information about mosquito control, please visit EPA's mosquito control page⁴. Furthermore, the EPA is actively working to complete the review and assessments of these chemicals as soon as possible to ensure transparency around the safe use of pesticides and EPA is sharing health and safety information with CDC and local authorities so that informed decisions about the use of pesticides in mosquito control programs can be made.

Sincerely,

Jack E. Housenger, Director
Office of Pesticide Programs
US Environmental Protection Agency

⁴ <https://www.epa.gov/mosquitocontrol>