



BEYOND PESTICIDES

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September 14, 2016

Jack Housenger
Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Dear Mr. Housenger,

As local and state officials implement mosquito abatement programs to address the Zika virus, it is critical that they have complete transparent information that they are not currently getting from the Environmental Protection Agency (EPA). This information, specific to residential exposure to the insecticides naled and its degradation product dichlorvos (DDVP), as well as synthetic pyrethroids, is necessary for officials on the ground to make fully informed decisions. Furthermore, with the elevated concerns about the virus and the pesticides being used, we are writing to urge the agency to expedite an updated registration review assessment for naled and DDVP, which is now overdue by at least two years. Until that updated review of naled/DDVP and synthetic pyrethroids is completed, and in light of the deficiencies in the agency's current assessment, we ask that the EPA immediately alert local and state officials around the country to the fact that EPA's key data review on safety is incomplete and the scientific literature raises safety concerns.

According to the agency's final work plan published in 2009,¹ phase 3 of naled's registration review decision was to be begin with the opening of the docket for public comment on the proposed registration review decision in 2014, with a final registration review decision in 2015. Given the widespread use of naled/DDVP for Zika in South Florida, Puerto Rico and other states and territories, it is imperative that an updated risk assessment be presented for public review and comment, given that there are important outstanding data and concerns regarding naled/DDVP exposures to residential bystanders.

Based on data needs described in the agency's 2009 work plan, new data for "comparative cholinesterase and UV absorption spectrum" was received by the agency since naled's 2002 Interim Reregistration Eligibility Decision (IRED) and 2006 Reregistration Eligibility Decision (RED), but has not been made public; it was supposed to be reviewed in the updated registration review assessment, which is overdue.

¹ USEPA. 2009. Naled Final Work Plan Registration Review. Office of Pesticide Programs. Washington DC.

Further, the agency indicated in its 2009 workplan that it will review “total residues of concern” to include dichlorvos (DDVP). Additionally, DDVP’s 2015 registration review is also overdue and updated assessments are needed. Residential exposures to DDVP as a consequence of naled/DDVP use for mosquito spraying is a reality, including potential post-application dermal and inhalation exposures. The agency notes, “Residential and occupational exposures to dichlorvos may also result from uses of naled...” even though EPA expects “that any dichlorvos formed dissipates rapidly.”² However, since residues of naled are converted in the body to DDVP,³ agency action on this exposure scenario is urgently needed. In DDVP’s 2006 registration document, the agency states that it “has determined that the adverse effects caused by dichlorvos that are of primary concern to human health are neurological effects related to inhibition of cholinesterase activity.”⁴ There is also “suggestive” evidence of DDVP’s carcinogenicity, which, along with its neurotoxicity, mutagenicity, and reproductive impacts, warrants an in-depth assessment of all DDVP’s aggregate exposures. EPA states that “any exposure to dichlorvos from the use of naled would be covered by the Naled Risk Assessment,” but this is undermined by the fact that both assessments for naled and DDVP are long overdue.

Even though the agency identifies the need for further review of naled/DDVP, specifically related to residential use for mosquito control, EPA and the Centers for Disease Control and Prevention (CDC) have made blanket statements of acceptable risk to the public, implying that the chemical exposures from mosquito spraying are perfectly safe. Upon review of the RED, we note that the agency states, “Individuals in residential areas can be exposed to naled as bystanders from mosquito/black fly control application, however EPA does not have risk concerns for these individuals,” (p. 9) and “Short- and intermediate-term residential bystander exposures resulting from wide area mosquito and black fly applications do not exceed EPA’s level of concern.” (p. 30)⁵ However, it appears that the basis for this conclusion concerning bystander risks is not drawn from data related to the current mosquito control exposure pattern, nor is it based on an aggregate risk assessment, taking into account other exposures to organophosphates, including DDVP, with a common mechanism of toxicity. In fact the agency’s reference seems to be the toxicological summary laid out in Table 5.⁶

In the *Occupational & Residential Handler Risk Summary* section (p. 17) part 2, of the RED, *Mosquito and Blackfly Application*, the agency states, “No data were submitted in support of the naled mosquito/blackfly applications. Additionally, scenario-specific data for these unique types of application are not available in [Pesticide Handlers Exposure Database, PHED]. However, as a range finding assessment, exposure information for the use of agricultural equipment available in PHED were used as a surrogate” (p. 22). The agency states that agricultural scenarios are assumed to be representative of mosquito/blackfly uses for

² USEPA. 2002. Interim Reregistration Eligibility Decision for Dichlorvos (DDVP). Office of Pesticide Programs. Washington DC.

³ Ibid.

⁴ Ibid.

⁵ USEPA. 2002. Interim Reregistration Eligibility Decision for Naled. Office of Pesticide Programs. Washington DC.

⁶ USEPA. 2006. Reregistration Eligibility Decision for Naled. Office of Pesticide Programs. Washington DC.

occupational handlers. There is uncertainty in using agricultural use scenarios as a surrogate for mosquito applicator uses, and the agency even notes that it “has insufficient data (emphasis added) to determine if exposures to pilots from agricultural aerial applications are similar to the exposures to pilots applying mosquito control agents.” Further, EPA’s identification of the need for restricted-entry intervals after agricultural applications poses a concern for both applicators and residential bystanders after mosquito/blackfly uses. Finally, EPA determined acceptability of exposure to pilots and handlers, assuming the use of personal protective equipment (PPE), such as respirators and double layers of clothing.

In the *Residential Post-Application Risk* section of its interim review, the agency considered “dermal exposures and incidental oral exposures (hand-to-mouth, object-to-mouth, and ingestion of soil) that could result from deposition of naled on turf” (p28) for residential bystander exposures, and subsequently finds that “dermal MOEs [margin of exposure] for post-application exposure for all aerial mosquito and blackfly application scenarios do not exceed EPA’s level of concern.” While the occupational assessment addressed dermal and inhalation exposures, despite several uncertainties in extrapolating from agricultural data, the agency does not identify a separate residential inhalation assessment, even though this is the primary route of human exposure resulting from mosquito applications. Comparatively, inhalation residential bystander assessments were done for another insecticide, malathion, for similar uses.⁷

It is critical that EPA disclose that it has not conducted inhalation residential bystander assessments for residential naled/DDVP exposures for mosquito/blackfly in support of statements from the agency and CDC that there are no risks to bystanders.

Other commonly used mosquito adulticides like the pyrethroids, including permethrin and phenothrin (sumithrin), must also have their assessments updated and completed, raising similar concerns about statements of safety. Several pyrethroids are associated with cancer, hormone disruption, and reproductive effects, and thus have hazard and exposure concerns regarding widespread application for mosquito control. Phenothrin for instance, “lacks acute, chronic, and developmental neurotoxicity studies that are required to fully evaluate risks to infants and children,”⁸ while for permethrin there are outstanding concerns regarding its developmental neurotoxicity.⁹ Additionally, we believe a consideration of all exposures are significant, especially dermal and inhalation residential exposures from pyrethroid mosquito uses, to support the conclusion made in the 2011 pyrethroid cumulative assessment that “estimated risks from existing pyrethrins/pyrethroid uses are not of concern.”¹⁰ As such, for the pyrethroid insecticides we urge the agency to conduct thorough assessments on exposures via mosquito spraying, and ask the agency to ensure that state and local officials have all the information regarding the potential hazards and uncertainties associated with the adulticides used in massive mosquito spraying.

⁷ USEPA. 2009. Reregistration Eligibility Decision (RED) for Malathion. Office of Pesticide Programs. Washington DC.

⁸ USEPA. 2008. Reregistration Eligibility Decision for d-Phenothrin. Office of Pesticide Programs. Washington DC.

⁹ USEPA. 2009. Reregistration Eligibility Decision (RED) for Permethrin. Office of Pesticide Programs. Washington DC.

¹⁰ USEPA. 2011. Pyrethroid Cumulative Assessment. Office of Pesticide Programs. Washington DC.

It is clear that the existing risk assessment for naled/DDVP are riddled with uncertainties, lack of data, and thus are inadequate to provide any confidence in the safety of the chemical's use in neighborhoods battling mosquito populations, for both residential bystanders and applicators/handlers. In 2012, the European Union banned naled citing "potential and unacceptable risk" to human health and the environment,¹¹ and we recommend that EPA follow a similar precautionary approach to widespread naled use. We urge the agency to immediately notify the public of the state of knowledge and regulatory uncertainties, pending the completion of an updated human health risk assessment that fully considers dermal and inhalation residential bystander exposures, as well as occupational exposures for public review, to naled/DDVP.

We appreciate your immediate attention to our request for full and open disclosure of the hazards, need for additional risk information, and delayed EPA review of pesticides that are being used for mosquito management, particularly those being used to address the Zika virus.

Sincerely,

Nichelle Harriott
Science and Regulatory Director

Jay Feldman
Executive Director

cc. Rick Keigwin, Jr. Deputy Director
Yu-Ting Guilaran, Director,
Pesticide Re-evaluation Division

¹¹ European Commission. COMMISSION DECISION of 11 May 2012 concerning the non-inclusion of naled for product type 18 in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (notified under document C(2012) 3050). Official Journal of the European Union. <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32012D0257&from=EN>.