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Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Submitted via email to: guerry.jacqueline@epa.gov

Attn: Docket No. EPA-HQ-OPP-2004-0385

Docket ID Number EPA-HQ-OPP-2004-0385: Permethrin Reregistration Eligibility Decision

The purpose of this letter is to comment on EPA's Reregistration Eligibility Decision (RED) for permethrin, which was made available for public comment on June 28, 2006 (71 FR 36788). Tri-TAC previously submitted comments on the preliminary risk assessments for permethrin on October 20, 2005 and we have attached a copy of the letter for your reference. Tri-TAC reiterates that we are pleased that EPA modeled permethrin impacts on the sewer system with an Aquatic Exposure, "Down-the-Drain" Assessment and encourages EPA to include a similar analysis during Registration Review for all pesticides with a pathway to the sewer. However, Tri-TAC continues to have concerns about the lack of mitigation measures proposed for permethrin uses that lead to sewer discharges since EPA's analysis show that "aquatic organisms appear to be at acute risk from exposure in surface waters containing permethrin from wastewater."¹ As background, Tri-TAC is a technical advisory group for Publicly Owned Treatment Works (POTWs) in California. It is jointly sponsored by the California Association of Sanitation Agencies, the California Water Environment Association, and the League of California Cities. The constituency base for Tri-TAC collects, treats, and reclaims more than two billion gallons of wastewater each day and serves most of the sewered population of California.

Mitigation Measures

In The Agency Revised Risk Assessment for the Reregistration Eligibility Decision on Permethrin After Public Comments, Phase III (Risk Assessment)

¹ EPA, The Agency Revised Risk Assessment for the Reregistration Eligibility Decision on Permethrin After Public Comments, Phase III, April 5, 2006, page 113

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Dated April 5, 2006, EPA concludes, after using conservative assumptions for the removal of permethrin from wastewater treatment and stream dilution factors, that the risk quotients generated in the Aquatic Exposure, "Down-the-Drain" Assessment "showed that permethrin residues from this process were a potential acute risk to aquatic freshwater and estuarine/marine invertebrates, as well as a potential acute risk to fish." Tri-TAC questions the justification for EPA's decision to reregister indoor products that discharge to the sewers without proposing any mitigation measures or label language changes in the RED to address the potential problems EPA identified. Tri-TAC requests that EPA mitigate the risks prior to reregistration of these products.

EPA justified reregistration of products that discharge to sewers in the RED Risk/Benefit Balancing Analysis by stating "with regard to the treatment of fabrics, permethrin is the only pesticide registered to pre-treat fabrics, which the Armed Forces Pest Management Board (AFPMB) strongly supports as a method of preventing many diseases that might afflict military personnel in the field." However, EPA did not perform a risk/benefit analysis justifying the reregistration of products used by the general public such as pet products, impregnated clothing, products to treat clothes, and over the counter and prescription drugs. Since the production volume for permethrin for specific uses is unpublished and classified as Confidential Business Information, Tri-TAC is unable to ascertain the amount of permethrin discharged to Publicly Owned Treatment Works (POTWs) in the United States from military battle dress compared to the amount of permethrin discharged from products used by the general public. Tri-TAC assumes that EPA has deferred the mitigation measures of discharge from products used by the general public until Registration Review, which will not occur until at least 2010.

The deferred mitigation of these products does not meet EPA's obligations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). POTWs are required to meet effluent aquatic toxicity standards in National Pollutant Discharge Elimination System (NPDES) permits, but POTWs do not have the ability to regulate discharges of pesticides from domestic sources. The risk/benefit analysis standards of FIFRA require that EPA ensure that pesticides are used in such a manner that Clean Water Act (CWA) water quality standards are maintained and aquatic habitats are protected. In the permethrin RED, EPA does not fulfill its responsibility because it does not propose actions to prevent acute risk to aquatic organisms from the exposure in surface waters containing permethrin from wastewater.

EPA's inaction may adversely affect POTWs. Pesticides can potentially interfere with treatment plant operation, ability to recycle reclaimed water and biosolids, and compliance with NPDES permit effluent limits. In addition to the adverse environmental impacts, non-compliance with CWA requirements can be extremely costly for POTWs. Costs are incurred for identifying the source of the pollutants causing non-compliance, source control to reduce impacts of the pollutants, and construction, operation, and maintenance costs to upgrade POTWs with advanced treatment to remove pollutants

that cannot be adequately reduced with source control. Also, when surface water bodies become impaired by pesticides, POTWs discharging to the water bodies can be impacted through additional requirements established as part of Total Maximum Daily Loads (TMDLs) set for the water bodies. The cost to POTWs to comply with TMDLs can be up to millions of dollars per water body per pollutant.

POTWs are also subject to mandatory minimum penalties for NPDES permit exceedences. In California, the Clean Water Enforcement Act requires the Regional Water Quality Controls Boards (Regional Boards) to assess penalties for each NPDES permit exceedence, whether or not the POTW has the authority to prevent the violation. In addition, the Regional Boards are required to continue to assess penalties until the POTW is in compliance with its NPDES permit.² Since POTWs do not have the authority to regulate pesticides, if a pesticide causes an NPDES permit exceedence, the POTW would be fined until the California Department of Pesticide Regulation, EPA, and/or Food and Drug Administration (FDA) regulates the pesticide. Nationwide, POTWs can also be subject to legal action for NPDES violations, thereby causing the POTW to pay legal fees, settlements, and/or judgments.

Tri-TAC requests that Aquatic Hazard Language be included on pet products, products to treat clothes, pre-impregnated clothing, over-the-counter and prescribed drugs to inform the users of these products of the significant risk to aquatic organisms from the sewer discharge of permethrin.

Aquatic Exposure, “Down-the-Drain” Assessment

In the permethrin RED, EPA did not consider the risks to aquatic organisms from POTWs that discharge to effluent dominated receiving waters and facilities nationwide that do not have dilution credits in their NPDES permits. As Tri-TAC mentioned in our previous comment letter, the Exposure and Fate Assessment Screening Tool (E-FAST) deliberately excludes facilities with stream dilution factors of 1.0 or less.³ In order to address Tri-TAC’s concern, in the Risk Assessment EPA calculated surface water quality concentrations in the Aquatic Exposure, “Down-the-Drain” Assessment for a scenario with no stream dilution factors; however, EPA failed to use these numbers in calculating acute and chronic risk for aquatic organisms.

² The Clean Water Enforcement Act states that mandatory minimum penalties shall not be assessed if the violations are caused by one or any combination of (1) an act of war, (2) an unanticipated, grave natural disaster or other natural phenomenon of an exceptional, inevitable, and irresistible character, the effects of which could not have been prevented or avoided by the exercise of due care or foresight, or (3) an intentional act of a third party, the effects of which could not have been prohibited or avoided by the exercise of due care or foresight, see California Water Code, Section 13385(j) for further details.

³ EPA, Exposure and Fate Assessment Screening Tool (E-FAST) Beta Version Documentation Manual, 1999

In addition, as detailed in Tri-TAC's previous letter, the use patterns of household products should be considered in the Risk Assessment when estimating the mass discharge of permethrin to sewers and calculating the high end surface water concentrations. In the Aquatic Exposure, "Down-the Drain" Assessment, EPA used the annual production volume of permethrin for household products divided by the U.S. population to estimate the daily per capita mass discharge rate. This estimate is appropriate to calculate chronic surface water concentrations.

However, to calculate acute surface water concentrations, a high end mass discharge rate should be utilized. The high end scenario should model surface water concentrations following a concentrated permethrin discharge to the sewer system. For example, EPA could choose to model the high end scenario such as additional loading of permethrin received at a POTW following an outbreak of head lice at a school. In response to Tri-TAC's comments EPA stated, "Since all the amount of permethrin that could possibly go "down-the-drain" was assumed to go that route, this exercise is not needed. The E-FAST "down-the-drain" module is designed for national assessments." For the high end scenario, EPA should have evaluated a scenario with no stream dilution factor and a concentrated permethrin discharge to the sewer system. This high end scenario could occur at any POTW in the nation that discharges to effluent dominated receiving waters or a POTW that does not have dilution credits in their NPDES permit; it is not specific to POTWs in California.

Production Volume

Tri-TAC respects the mandate for EPA to keep production volume of permethrin for specific uses from public disclosure. However, since this data is Confidential Business Information, Tri-TAC is unable to verify the information. Tri-TAC notes that the preliminary risk assessments for permethrin which were released for public comment on August 31, 2005 state that production volumes for pet products, products to treat clothes, pre-impregnated clothing, over-the-counter and prescribed drugs obtained from unpublished marketing data, partly from the FDA, the technical registrants, and the Biological and Economic Analysis Division indicated that on an average basis 6,120,000 Kg active ingredient permethrin is used per year. However, the RED released in June 2006, less than a year later, citing the same sources states that 252,000 Kg active ingredient of permethrin is used per year for the same products.

POTWs have noticed an increase in the publicity of permethrin-impregnated products, including articles printed in Reader's Digest and Westways Magazine, as well as advertisements by clothing manufacturers for permethrin-impregnated clothing. Alameda County noted in a summer 2006 press release that pre-impregnated clothing could be used to prevent West Nile virus infections. Tri-TAC expects that more permethrin-impregnated products have been purchased as a result of the publicity thereby increasing the discharge of permethrin to sewers and the probability of aquatic

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toxicity problems. It is highly unlikely that permethrin use has dropped an order of magnitude in one year.

The amount of permethrin used per year in the Aquatic Exposure, "Down-the-Drain" Analysis directly correlates to the risk predicted for aquatic organisms. Tri-TAC requests that EPA share production volume data with POTWs and state government environmental agencies, which are also by law able to keep Confidential Business Information and unpublished marketing data confidential, in order to properly review Aquatic Exposure, "Down-the-Drain" Assessments performed by EPA.

In conclusion, sewerage agencies need EPA's assistance to protect surface waters from contamination from permethrin. POTWs are required by NPDES permits to meet effluent aquatic toxicity standards; however, POTWs do not have the authority to regulate pesticides. The Aquatic Exposure, "Down-the-Drain" Assessment conducted for permethrin clearly shows that aquatic impacts could occur from the use of permethrin in consumer products and that timely action is needed by EPA to mitigate the risks. Tri-TAC requests that EPA impose mitigation measure and label language changes prior to the reregistration of permethrin products for uses that discharge to sewers.

Tri-TAC appreciates the opportunity to comment on the permethrin RED. If you have any questions or require additional information, please contact Ms. Preeti Ghuman by phone at (562) 699-7411, extension 2904 or by email at pghuman@lacs.org.

Sincerely,



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Chair, Tri-TAC

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