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Public Information and Records Integrity Branch (PIRB) (7502C)
Office of Pesticide Programs (OPP)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460
Attn: Docket ID Number OPP-2005-0043

Submitted electronically

Docket No. OPP-2005-0043- Pyrethrins Revised Risk Assessments

The purpose of this letter is to comment on EPA's risk assessments for pyrethrins, which were made available for public comment on September 21, 2005 (70 FR 55378). Pyrethrins are a mixture of naturally occurring insecticides derived from the flowers of *Chrysanthemum cinerariaefolium* and *Chrysanthemum cineum*. Tri-TAC previously submitted comments regarding the pyrethrins risk assessments on June 27, 2005; however, our concerns were not addressed in the revised risk assessments. We are concerned that the revised risk assessments do not evaluate the potential adverse water quality impacts associated with sewer discharges of pyrethrins, particularly pyrethrins used in pet shampoos, head lice shampoos, and other indoor-use products. 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.

Indoor Uses, Including Pet Shampoos

While the EPA revised risk assessments for pyrethrins consider potential adverse water quality impacts arising from agricultural and mosquito abatement uses, they do not consider such impacts from pyrethrins usage in

pet shampoos and other indoor use products. According to EPA, 85% of pyrethrins are used in indoor settings. Only 9% are used on agricultural commodities and 6% on terrestrial non-food areas (including mosquito abatement applications).[1] We requested in our previous letter that EPA evaluate potential adverse water quality impacts from sewer discharges of pyrethrins in the revised risk assessments since the vast majority of pyrethrins are used in indoor settings.

The normal use of pet shampoos includes a direct pathway to sewers, from rinsing of the shampoo after application. Even when pets are rinsed outdoors, the rinse water can enter storm drains or flow directly to creeks and rivers. EPA's Environmental Fate and Effects Division (EFED) recommends that the label on pyrethrins for end use products contain the language "Do not contaminate water when disposing of equipment wash-waters or rinsate." This proposed language does not offer any suggestions for disposal of shampoo rinse water that is generated during normal usage of pet shampoos. The rinse water must either be allowed to run off to storm drains or be put in sewers; in either case there is a pathway for water contamination.

EPA responded to Tri-TAC's request to evaluate the potential water quality impacts from sewer discharges of pyrethrins in the Response to Public Comments on the Drinking Waters Assessment for Pyrethrins (Memorandum) dated September 6, 2005. In the Memorandum, EPA states, "The EFED's assumptions to determine exposure for drinking waters and ecological effects are designed to be protective of the environment. Those uses that involve exposure to wildlife are weighed more heavily (for example, the agricultural uses and the mosquito abatement)." Tri-TAC does not understand EPA's logic in weighing wildlife exposure from agricultural uses and mosquito abatement more heavily than exposure from indoor uses when 85% of the pyrethrins are used in indoor settings. EPA should not ignore potential adverse water quality impacts from the largest uses of pyrethrins.

EPA also states in the Memorandum, "The EFED acknowledges that there are certain products, such as head lice treatment and pet shampoos, that may result in consumer disposal in wastewaters from household uses. Recently, the EFED conducted a national screening level assessment of a chemical (permethrin) that had numerous products, in addition to head lice treatment and pet shampoos, that could result in disposal in wastewaters from household uses. According to a modeling approach (EPISUITE), pyrethrins appear to have a better level of removal than permethrin in wastewater treatment plants. Nevertheless, the ecological analysis results from permethrin were of similar order of magnitude or lower than the results obtained for agricultural products." Tri-TAC concurs that EFED recently conducted an Aquatic Exposure, "Down-the-Drain" Assessment for permethrin; however, there is no scientific justification for relying on the aquatic exposure assessment for permethrin to estimate ecological effects from

[1] EPA, Overview of the Pyrethrins Risk Assessments, April 27, 2005.

pyrethrins since they have different use rates and environmental fates. The majority of pyrethrins discharged to sewers should be removed during wastewater treatment because pyrethrins bind well to solids. However, not all solids are removed during treatment so some pyrethrins will pass through such treatment into receiving waters. In receiving waters, the pyrethrins are expected to bind to sediments and can potentially impact benthic communities. POTWs could then be impacted, either through more stringent discharge limitations or through the Total Maximum Daily Load process.

Tri-TAC has provided comments to EPA about the method used to translate wastewater treatment plant discharge concentrations from the Exposure and Fate Assessment Screening Tool into acute and chronic surface water concentrations and the use of a daily per capita mass discharge rate to calculate acute surface water concentrations used in the Aquatic Exposure, "Down-the-Drain" Assessment for permethrin. Even with the conservative assumptions used by EPA, the model results show that acute and chronic levels of concern for aquatic organisms were exceeded as a result of "down-the-drain" uses of permethrin. This result is significant because POTWs do not have the ability to regulate discharges of pesticides; however, POTWs are required to meet effluent aquatic toxicity standards in National Pollutant Discharge Elimination System (NPDES) permits.

Tri-TAC requests that EPA conduct an analysis for the "down-the-drain" uses of pyrethrins, especially since EPA states in the Overview of the Pyrethrins Risk Assessment dated April 27, 2005 that the levels of concern were exceeded from the agricultural use of pyrethrins for acute risk to freshwater and estuarine/marine fish and invertebrates, chronic risk to estuarine/marine invertebrates, and acute and chronic risk to estuarine/marine sediment dwelling organisms. Therefore, it is possible that the levels of concern will also be exceeded from the use of consumer products containing pyrethrins.

Head Lice Treatment (Pediculicide) Uses

Pyrethrins are commonly used in head lice shampoos that are applied directly to humans. For example, RID Lice Killing Shampoo and RID Lice Killing Mousse both contain 0.33% pyrethrins. When these shampoos are rinsed after use, they will flow directly to sewers. Although pediculicide uses of pesticides are not currently subject to regulation under FIFRA, they were subject to such regulation until 1979. Since pediculicides are considered to be drugs, they are also subject to the Federal Food, Drug and Cosmetic Act (FFDCA). On November 5, 1979 (44 Federal Register, 63749), EPA decided to exempt pediculicides from the requirements of the FIFRA. The regulation of these products under both the FIFRA and the FFDCA was felt to be duplicative, as stated in the announcement of the exemption, "EPA and FDA concluded that the dual review of pesticide/new drug products offered solely for human use represents an expensive duplication of time and resources for both the Agencies and

the sponsors of these products without any significant increase in benefits to public health and/or the environment. It is further concluded that regulations of these products solely by FDA under the FFDCA would adequately serve the intent of FIFRA."

Regulation under the FIFRA and the FFDCA is no longer duplicative. Since 1979, the degree of regulation under FIFRA has changed considerably, most notably with passage of the Food Quality and Protection Act of 1996 (FQPA). This statute requires EPA to review all pesticide registrations on at least a fifteen-year cycle (7 U.S.C. §136a(g)(1)(A)). The goal of this requirement is to ensure that all pesticides continue to meet up-to-date standards for safety, public health, and environmental protection. EPA has the authority to require data and take action if needed between registration cycles (7 U.S.C. §136a(c)(2)(B); §136a-1(d)(3)). No similar provisions exist under the FFDCA. Additionally, EPA has emergency suspension authority, which means a pesticide registration can be canceled immediately if there is an emergency, imminent threat to public health or the environment (7 U.S.C. §136d(c)). This appears to be a much more direct and powerful tool to regulate pesticides when compared to the FDA's authority to simply require an Environmental Assessment in such circumstances.

It is Tri-TAC's position that EPA should reassert its control over pediculicides under the FIFRA. As such action is beyond the scope of the action EPA is currently considering, EPA should, at minimum, consider the environmental impacts of these treatments in its revised risk assessments. Under the FIFRA, EPA has a statutory responsibility to ensure that pesticides are safe and effective for their intended uses and to prevent unreasonable adverse effects to man, other animals, and the environment from their usage (7 U.S.C. §136(bb), §136a(a), §136a(d)(2); §136d(b)). By ignoring the water quality risks posed by pyrethrins-containing head lice treatments, EPA is not fulfilling its statutory responsibility.

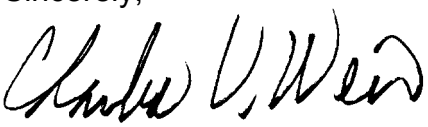
In conclusion, POTWs need EPA's assistance to protect surface waters from contamination from pyrethrins. As previously discussed, POTWs are required by NPDES permits to meet aquatic toxicity standards but do not have the authority to regulate pesticides. Tri-TAC requests EPA conduct an Aquatic Exposure, "Down-the-Drain" Assessment, similar to the analysis performed for permethrin, to evaluate potential aquatic toxicity impacts from the use of pyrethrins in consumer products with pathways to the sewer. If the model shows that acute and chronic levels of concern for aquatic organisms are exceeded from the indoor uses of pyrethrins, Tri-TAC requests that EPA propose mitigation measures for pyrethrins during reregistration.

Contact Information

Tri-TAC appreciates this opportunity to comment on the revised risk assessments for pyrethrins. If you have any questions about this letter or require additional information,

please contact Ms. Preeti Ghuman by phone at (562) 699-7411, extension 2904, or by e-mail at pghuman@lacsd.org.

Sincerely,



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