

November 15, 2002

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW.
Washington, DC 20640

Docket ID Number OPP-2002-0202 – Lindane Reregistration Eligibility Decision (RED)

The purpose of this letter is to comment on EPA's Lindane Reregistration Eligibility Decision (RED), which was made available for public comment on September 23, 2002 (67 FR 59500). The County Sanitation Districts of Los Angeles County (Districts) are concerned that the Reregistration Eligibility Decision may set dangerous precedents regarding pesticides and water quality. In particular, the Districts are concerned about the methodology used to determine estimated concentrations of lindane in surface water from use and disposal of lindane shampoos and lotions. Additionally, the Districts are concerned about the failure of the EPA Office of Pesticide Programs (OPP) to use legally promulgated water quality criteria and standards as its basis for acceptable surface water lindane concentrations.

Background

The Districts are a confederation of 25 independent special districts that serve the water pollution control and solid waste management needs of over five million people in Los Angeles County, California. Seventeen of the districts have collectively constructed an extensive regional sewerage system known as the Joint Outfall System (JOS), which conveys and treats approximately 450 million gallons per day (MGD) of wastewater from 78 cities and unincorporated county areas. The JOS consists of seven treatment/water reclamation plants and 1,200 miles of large diameter trunk sewers that form a network connecting the treatment plants and ocean outfalls off Whites Point on the Palos Verdes Peninsula. The Districts also operate four water reclamation plants in northern Los Angeles County serving the communities in and around the cities of Santa Clarita, Lancaster and Palmdale. On an annual basis, over 50 MGD of reclaimed water is reused for applications including groundwater recharge, landscape irrigation and industrial uses. The remainder is discharged to inland surface waters that are effluent dependent water bodies. The beneficial uses of the receiving waters are diverse and include municipal and industrial water supply, groundwater recharge, water recreation, warm fresh water habitat, wildlife habitat, commercial and sport fishing, and rare, threatened or endangered species spawning, reproduction, and early development. Solid material removed during treatment is digested and dewatered. The resulting biosolids are either landfilled or

beneficially reused for agricultural land application.

The Districts are concerned about discharges of lindane from their wastewater treatment plants. Water quality standards for California's inland surface waters and enclosed bays and estuaries were promulgated by the Environmental Protection Agency in May 2000¹. These standards are known as the California Toxics Rule and establish water quality criteria for the protection of aquatic life and human health. In the latter case, the criteria are intended to minimize the adverse human health effects due to substances in ambient water. The California Toxics Rule established a criterion of 19 ppt lindane for protection of human health via consumption of water and aquatic organisms (for water bodies used or potentially used as drinking water sources), and a criterion of 63 ppt for protection of human health via consumption of aquatic organisms only (for all other water bodies). **The 19 ppt and 63 ppt criteria for lindane are also EPA's legally adopted national water quality criteria, so this is not simply a California issue.**²

Because lindane is a highly regulated pesticide, the routes for it to enter sewerage systems are extremely limited. The main pathway is from human treatments for lice and scabies with lindane-containing products. A typical lice or scabies treatment uses one to two ounces of the one percent lotion, or approximately 0.015 ounces of the lindane active ingredient. That is enough lindane to pollute 6 million gallons of water to the 19 ppt standard or 2 million gallons to the 63 ppt standard.

In order to reduce lindane loadings to our sewerage system, we pursued a ban on the sale and use of lindane-containing lice and scabies prescriptions in California that took effect January 1, 2002. However, we continue to see detectable amounts of lindane entering our sewers. The continuing lindane loadings may be coming from pharmacies or consumers that are not aware of the ban and from lindane lice and scabies products that have entered California from out-of-state. As a single lice or scabies treatment contains enough lindane to pollute six million gallons of water to the 19 ppt standard or two million gallons to the 63 ppt standard, one or two treatments could cause a discharge violation at a smaller POTW. Therefore, even small amounts of lindane entering California from out-of-state are of concern.

Specific Comments

Specific comments on the Reregistration Eligibility Decision for Lindane and supporting documents follow. Each comment begins with the specific document, page, and language upon which comments are being made.

1. *Agency Response to Phase V Comments on Lindane, p. 2.* **“Further, the Agency assessed both human health and environmental risk from disposal of [lindane] pharmaceutical products after application/use ”** We applaud the EPA for taking this important step. Even though the Food and

¹ Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Rule. May 18, 2000 *Federal Register*; 31682.

² Nationally Recommended Water Quality Criteria; Notice. December 7, 1998 *Federal Register*; 67548.

Drug Administration (FDA) is currently responsible for the regulation of pharmaceutical lindane, it is important that all sources of a pesticide be considered when making decisions about the environmental impact of the pesticide. The Districts encourage the EPA to consider pharmaceutical uses when reregistering other pesticides with pharmaceutical uses, such as malathion, permethrin, and pyrethrin.

2. *Agency Response to Phase V Comments on Lindane*, p. 2. **“EPA determined that when disposed to sewer systems, the concentration of lindane (using actual measured data from wastewater treatment plant outflows) was several orders of magnitude below the level that would raise a concern for environment effects, or for human health effects if that water was used as a source of drinking water.”** This statement is inconsistent with the methodology for surface water concentration estimation as presented in the EPA memorandum, “Estimated Concentrations of Lindane in Surface Water Used as Source of Drinking Water from Use and Disposal of Shampoo and Lotion Into Household Wastewater,” that was used to perform the calculations. The memorandum relied upon sales rates of lindane pharmaceuticals and theoretical calculations to determine lindane loadings to surface waters, not actual effluent concentrations at a POTW. The Districts encourage the use of actual POTW values in place of theoretical calculations, as there is much less uncertainty in actual POTW values. Where actual values are available, it does not make sense to use theoretical calculations.

Additionally, while EPA took an important step forward by looking at human health effects from the discharge of lindane to water bodies that are used as sources of drinking water, EPA neglected to examine the human health effects of water bodies that are not sources of drinking water. For water bodies that are not current or potential sources of drinking water, EPA has established a lindane criterion of 63 ppt, based on consumption of aquatic organisms in the water body. To complete its assessment of the environmental impact of disposal of pharmaceutical lindane to the sewer system, EPA must consider water bodies that are not sources of drinking water.

3. *Agency Response to Phase V Comments on Lindane*, p. 5. **“The Agency used an exposure model and reported lindane concentrations in discharged effluent (0.03 ppb) from the Publically [sic] Owned Treatment Works (POTWs) of Sanitation Districts of Los Angeles County, California to assess the risks associated with estimated concentrations of lindane in surface water from consumer use for both lice and scabies treatments.”** As stated in Comment 2, EPA in fact used theoretical calculations in place of actual POTW effluent values, although the actual POTW effluent values were available to EPA. The Districts encourage the use of actual data in place of theoretical calculations wherever possible.
4. *Agency Response to Phase V Comments on Lindane*, p.6. **“As part of this process, there is a possibility that the WQS [Water Quality Standard] and/or the WQC [water quality criterion set by EPA’s Office of Water] could change. The assessment completed for both the lindane RED which is based on the revised cancer classification, and the Office of Water’s 1991 MCLG which is not based on the new draft guidelines but uses the 1986 cancer classification**

scheme, will likely be considered in a re-evaluation of WQSs by states and/or the WQC by USEPA as necessary. OW is also required to revisit or re-evaluate existing National Primary Drinking Water Regulations (MCLs/MCLGs) every six years. Although it is not certain whether changes to a [sic] states' WQS for lindane will occur, recent information suggests that the WQS could be increased.” We are extremely concerned that the EPA has chosen to reject the use of its own legally adopted surface water quality standards in performing its risk assessments for lindane, as well as ignoring enforceable water quality standards promulgated by the EPA in the California Toxics Rule. The EPA Office of Pesticide Programs (OPP) should recognize that EPA itself developed and adopted these standards and has an obligation to uphold them. We have received no word of any plans to change either the adopted federal water quality criteria for lindane nor the EPA-required California water quality standards promulgated in the California Toxics Rule.

A reference to the speculative possibility of regulatory changes resulting in a possible increase in the federal water quality criteria for lindane and the enforceable water quality standards for lindane in each of the fifty states does not constitute an appropriate basis for a regulatory action. While it is appropriate for the EPA Offices to work together to modify water quality criteria and standards to address information obtained in pesticide regulatory processes, it is never appropriate for an EPA Office to complete a regulatory action that allows uses of a pesticide at a rate that will cause violations of EPA's adopted water quality standards.

POTWs have to meet surface water quality standards for a variety of pollutants, including pesticides. Meeting such standards could become very difficult if EPA's OPP chooses to ignore them in determining which pesticides have the potential to cause water quality problems. The Office of Water does not have the statutory authority to restrict pesticide uses to protect water quality; it is the responsibility of the OPP to provide such protection. The OPP must base its regulatory decisions on legally promulgated water quality criteria to avoid POTWs being put in a position of having to comply with water quality criteria and standards without having the regulatory authority to attain such compliance.

If new information available to the OPP suggests that the currently enforceable water quality standards are inappropriate, OPP needs to work with the EPA Office of Water to adopt a joint regulatory course of action prior to reregistration of lindane. Such joint action could be either the use of the current water quality criteria in the lindane risk assessment or revision of the water quality criteria and all EPA-promulgated state water quality standards to reflect the new information.

5. *Estimated Concentrations of Lindane in Surface Water Used as a Source of Drinking Water From Use and Disposal of Shampoo and Lotion into Household Wastewater, p.1.* **“This memo presents the screening estimated concentrations of lindane in surface water used as a source of drinking water from consumer use for both lice and scabies treatments.”** The EPA OPP needs to prepare a parallel document that considers the concentrations of lindane in surface waters that

are **not** sources of drinking water from consumer use of lice and scabies treatments. The appropriate legally adopted national water quality criterion is 63 ppt.³

6. *Estimated Concentrations of Lindane in Surface Water Used as a Source of Drinking Water From Use and Disposal of Shampoo and Lotion into Household Wastewater, p.1.* **“Surface water concentrations were based on the estimated annual production volume directed to this market and released into household wastewater from products containing lindane at a maximum concentration of 1 percent. Exposures are further based on the effects of treatment in a Publically [sic] Owned Treatment Works (POTW) with a minimum of secondary treatment using either trickling filter or activated sludge bioreactors. Both daily per capita release into the waste stream and the daily per capita wastewater volume release are used in estimating time-averaged surface water concentrations.”** The Districts strongly recommend the use of actual data in place of estimates and theoretical models wherever possible. Concentrations of lindane in the influent and effluent of the Districts’ wastewater treatment plants were submitted to EPA, and could have been used for this purpose. Additional information regarding POTW discharges of lindane could have been readily obtained, as many POTWs are required under their National Pollutant Discharge Elimination System (NPDES) permits to collect and report such information.

The data submitted to the EPA by the Districts included 474 influent lindane samples and 743 effluent lindane samples, taken from January 1, 1990 to December 31, 1999 at the Districts’ twelve wastewater treatment plants. While the average values obtained by OPP using the theoretical models to agree well with average values in the Districts’ data, the OPP model does not account for the significant variability in the actual data.

7. *Estimated Concentrations of Lindane in Surface Water Used as a Source of Drinking Water From Use and Disposal of Shampoo and Lotion into Household Wastewater, p.2.* **“The EFED [Environmental Fate and Effects Division of OPP] does not possess a method nor has it traditionally conducted exposure assessments for the released [sic] of pesticides to domestic wastewater from consumer uses.”** The Districts appreciate OPP finally starting to consider this important pathway by which pesticides may enter surface water bodies, and encourage this pathway to be considered in all pesticide risk assessments.
8. *Estimated Concentrations of Lindane in Surface Water Used as a Source of Drinking Water From Use and Disposal of Shampoo and Lotion into Household Wastewater, p. 2.* **“The method [to determine lindane concentrations entering surface waters from pharmaceutical lindane use] assumes that in a given year the entire production volume is parceled out on a daily basis to the U.S. population and converted to a mass release per capita; daily per capita release of lindane to a wastewater treatment facility (gm/person/day). This mass is then diluted into the average daily volume of wastewater released per person daily to arrive at an estimated concentration of lindane in wastewater prior to entering a treatment facility. Lindane**

³ Nationally Recommended Water Quality Criteria; Notice. December 7, 1998 *Federal Register*, 67548.

concentration in untreated wastewater is then reduced by the fraction removed during wastewater treatment processes before release into a river or stream.” This method, while it was quite accurate at predicting the average effluent concentrations seen at the Districts’ treatment plants, does not account for the significant variability in discharge concentrations of lindane at real world POTWs. Lindane is used to treat head lice and scabies, which are contagious. As with other contagious conditions, the incidence is not neatly spread evenly among the entire populace but rather clustered in areas where outbreaks are occurring. Lindane usage, and hence discharge concentrations, will be significantly higher in areas where outbreaks are occurring than in areas where they are not. This variability needs to be taken into account when performing the calculations.

The most accurate method for EPA to account for this variability would be to use the significant collection of POTW data submitted to EPA by the Districts. A review of these data indicates that, while average effluent lindane concentrations among the wastewater treatment plants varied from 10 ppt to 40 ppt, maximum effluent lindane concentrations up to 340 ppt were recorded. Current lindane limits that are being set in the our NPDES permits for our non-ocean discharging treatment plants are 63 ppt, based on human health considerations for consumption of aquatic organisms in the surface waters receiving treatment plant effluent. The effluent data at the treatment plants from 1990 through 1999 indicate that the 63 ppt standard was exceeded ten times during this period. Without the ban on pharmaceutical uses of lindane that has been enacted in California, it is expected that we would violate the 63 ppt standard on an approximately yearly basis. POTWs not located in California that discharge to effluent-dominated water bodies are expected to have serious compliance problems meeting water-quality based effluent limits for lindane, even if the water bodies are not designated as existing or potential drinking water sources. It is puzzling how EPA could find that lindane concentrations entering surface waters from pharmaceutical products are acceptable, when even the most simple analysis indicates that there will be significant problems in some areas.

9. *Estimated Concentrations of Lindane in Surface Water Used as a Source of Drinking Water From Use and Disposal of Shampoo and Lotion into Household Wastewater, p. 2.* **“After estimating removal in wastewater treatment the remaining pesticide is discharged and instantaneously diluted into surface water where no further removal occurs.”** Lindane is a persistent, bioaccumulative, and toxic substance. As such, the EPA Office of Water has been considering disallowance of “credit” for dilution when it is discharged. OPP staff should contact Office of Water staff for more information.
10. *Estimated Concentrations of Lindane in Surface Water Used as a Source of Drinking Water From Use and Disposal of Shampoo and Lotion into Household Wastewater, p. 4.* **“For this purpose [calculating stream dilution], facilities with SDFs [Stream Dilution Factors] of 1.0 and less are deleted because wastewater flow dominates stream flow and is unlikely to be a local source of drinking water.”** An SDF of 1.0 or less represents a situation in which the flow in a receiving stream is less than or equal to the volume of a POTW’s discharge to it. Although the OPP may feel that it is unlikely for streams with SDF less than or equal 1.0 to be used as drinking water

sources, states have the actual authority to designate the beneficial uses of surface water bodies. POTWs must comply with state designations regarding beneficial uses of surface water bodies, not with the opinion of OPP.

Additionally, the discharge of pharmaceutical lindane to surface water bodies that are not drinking water sources needs to be considered. As indicated above, EPA's legally promulgated national water quality criterion for lindane in water bodies that are not drinking water sources is 63 ppt, based on human health considerations for the consumption of aquatic organisms living in the water bodies. In calculating expected surface water concentrations of lindane in receiving waters, OPP can not neglect streams with SDFs less than 1.0, as people do consume fish taken in effluent-dominated water bodies. Assuming no stream dilution is available, then the Districts' data indicate that the expected surface water concentrations of lindane would be 10 to 40 ppt on a long-term average, with concentrations up to 340 ppt. Variability in the discharge data result in routine exceedances of the 63 ppt standard.

11. *Estimated Concentrations of Lindane in Surface Water Used as a Source of Drinking Water From Use and Disposal of Shampoo and Lotion into Household Wastewater, p.4.* **“Mean SDFs for the 10th and 50th percentile treatment facility are recommended for use in acute and chronic risk assessments.”** The application of the 10th and 50th stream dilution values to determine acute and chronic risks is inappropriate. Acute risk is generally defined as a risk based on short-term exposure, not a risk based on having your drinking water coming from a lower flow stream. People consuming drinking water from 10th percentile streams will be exposed to the lindane concentrations in the water over a long-term, chronic basis. To determine acute and chronic risks, EPA should look at actual variability in POTW effluent lindane concentrations. The hundreds of data points on effluent lindane concentrations at the Districts' POTW that EPA has available can be used to develop statistics on variability. The variability statistics can then be applied to mean discharge values to determine appropriate acute and chronic risk levels.
12. *Reregistration Eligibility Decision for Lindane, p. ix.* **“The Agency also assessed the risks associated with estimated concentrations of lindane in surface water used as a source of drinking water which might result from consumer use of lindane for both lice and scabies treatments. Based on the reported lindane concentrations of discharged effluent from water treatment facilities in California used in a model to predict dilution in receiving streams, the acute and chronic DWECs are extremely low (10⁻⁵ to 10⁻⁴ ppb range).”** As stated in Comment 2, actual POTW data were not used in developing the DWECs but rather a theoretical model was used that ignored the significant variability in the POTW effluent lindane concentrations. Additionally, as describe in previous comments, dilution was inappropriately considered in the analysis.
13. *Reregistration Eligibility Decision for Lindane, p. 56.* **“The Agency believes that a conservative approach was used to estimate acute and chronic DWECs, because of the instantaneous and upper-end stream dilution factors that were assumed in the assessment.”** The Districts do not concur that the risk assessment was conservative. The risk assessment is clearly

not conservative enough, as it found no problem with pharmaceutical lindane being discharged to sewers at rates that clearly violate legally promulgated water quality criteria.

Contact Information

The Districts appreciate your consideration of our comments. If you have any questions about this letter or require additional information, please contact Ann Heil of the Sanitation Districts' Industrial Waste Section by phone at 562/699-7411, extension 2950, or by e-mail at aheil@lacsdsd.org.

Very truly yours,

James F. Stahl

Paul C. Martyn
Head, Industrial Waste Section

PCM:ATH:dfd

Cc:

Stephen Johnson, Assistant Administrator
Office of Prevention, Pesticides and Toxic
Substances (OPPTS)
U.S. EPA Headquarters 7101M
Ariel Rios Building
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

Marcia Mulkey, Director
Office of Pesticide Programs
U.S. EPA Headquarters 7501C
Ariel Rios Building
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

Lois Rossi, Director
Special Review and Reregistration Division
U.S. EPA Headquarters 7508C
Ariel Rios Building
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

Steven Bradbury, Acting Director
Environmental Fate and Effects Division
U.S. EPA Headquarters 7507C
Ariel Rios Building
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

Janet Andersen, Director
Biopesticides and Pollution Prevention Division
U.S. EPA Headquarters 7511C
Ariel Rios Building
1200 Pennsylvania Ave NW
Washington, DC 20460

Arthur-Jean B Williams, Branch Chief
Government International Services Branch
Field and External Affairs Division
U.S. EPA Headquarters 7506C
Ariel Rios Building
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

Deborah Sisco, Branch Chief
Environmental Field Branch
Field and External Affairs Division
U.S. EPA Headquarters 7506C
Ariel Rios Building
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

Tracy Mehan, Assistant Administrator
Office of Water
U.S. EPA Headquarters 4101M
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Benjamin Grumbles, Deputy Assistant
Administrator
Office of Water
U.S. EPA Headquarters 4101M
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

James Hanlon, Director
Office of Wastewater Management
U.S. EPA Headquarters 4201M
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Robert H. Wayland, Director
Office of Wetlands, Oceans, and Watersheds
U.S. EPA Headquarters 4501T
Ariel Rios Building
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

Geoffrey H Grubbs, Director
Office of Science and Technology
USEPA Headquarters 4301T
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460

Wayne Nastri,
Administrator, Region IX
U.S. EPA
75 Hawthorne Street
San Francisco, CA 94105

Alexis Strauss
Water Division Director
U.S. EPA
75 Hawthorne Street
San Francisco, CA 94105

Deborah Altschuler
President
National Pediculosis Association
P.O. Box 610189
Newton, MA 02461

Celeste Cantu
Executive Director
California State Water Resources Control

Board
1001 I Street
Sacramento, CA 95814

Dennis Dickerson
Executive Officer
California Regional Water Quality Control
Board, Los Angeles Region
320 West 4th Street #200
Los Angeles, CA 90013