

systems, liquids restrictions, and recordkeeping requirements.

4. Compliance with the design criteria of 40 CFR 258.40.

5. Compliance with the requirements of 40 CFR 258.50, 258.51, 258.53, 258.54, and 258.55 which pertain to groundwater monitoring and the requirements of 40 CFR 258.56, 258.57, and 258.58 which pertain to corrective action.

6. Compliance with the closure and post-closure criteria of 40 CFR 258.60 and 258.61.

7. Compliance with the financial assurance criteria of 40 CFR 258.73, which pertain to financial assurance for corrective action.

Vermont's Department of Environmental Conservation requires all existing MSWLFs to have either an existing permit or a temporary permit, both of which require compliance with the Federal Criteria in 40 CFR part 258 pursuant to state laws and regulations, found at Title 10 of the Vermont Statutes Annotated (V.S.A.) Chapters 159, 201 and 211, and 4 V.S.A. Chapter 27. The State of Vermont is not asserting jurisdiction over Indian land recognized by the United States government for the purpose of this notice. Tribes recognized by the United States government are also required to comply with the terms and conditions found at 40 CFR part 258.

EPA will consider all public comments on its tentative determination received during the public comment period and during any public hearing held. Issues raised by those comments may be the basis for a determination of inadequacy for Vermont's program. EPA will make a final decision on approval of the State of Vermont's program and will give notice of the final determination in the **Federal Register**. The notice shall include a summary of the reasons for the final determination and a response to all significant comments.

Section 4005(a) of RCRA, 42 U.S.C. 6945(a), provides that citizens may use the citizen suit provisions of section 7002 of RCRA, 42 U.S.C. 6972, to enforce the Federal Criteria in 40 CFR part 258 independent of any State/Tribal enforcement program. As EPA explained in the preamble to the final MSWLF criteria, EPA expects that any owner or operator complying with provisions in a State/Tribal program approved by EPA should be considered to be in compliance with the Federal Criteria. See, 56 FR 50978, 50995 (October 9, 1991).

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this notice from the requirements of section 6 of Executive Order 12866.

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this approval will not have a significant economic impact on a substantial number of small entities. It does not impose any new burdens on small entities. This notice, therefore, does not require a regulatory flexibility analysis.

Authority: This notice is issued under the authority of Section 4005 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6945.

Dated: July 17, 1995.

John P. DeVillars,

Regional Administrator.

[FR Doc. 95-18375 Filed 7-25-95; 8:45 am]

BILLING CODE 6560-50-P

[OPP-30000/10I; FRL-4944-4]

Lindane: Decision Not To Initiate a Special Review on Kidney Effects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA (the Agency) announces its decision not to initiate a Special Review for pesticide products containing lindane based on worker health concerns arising from studies showing irreversible renal effects in the rat. EPA has determined that these effects occur only in the kidneys of the male rat and are not relevant for human risk assessment. The Agency is currently developing a strategy to examine the role organochlorine chemicals, such as lindane, may play as endocrine disrupters. Should the Agency determine that this or other effects cause unacceptable risk, it will take appropriate regulatory action.

FOR FURTHER INFORMATION CONTACT: By mail, David H. Chen, Special Review and Reregistration Division (7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Special Review Branch, Rm. WF32C6, Crystal Station #1, 2800 Crystal Drive, Arlington, VA., telephone Number: 703-308-8017, internet e-mail address: chen.david@epamail.epa.gov

SUPPLEMENTARY INFORMATION: On March 18, 1994, EPA announced its proposed decision (and solicitation for public

comment) not to initiate a Special Review of lindane for male rat kidney effects described in the September 18, 1985 preliminary notification to lindane registrants and applicants. The Agency has reviewed the available data in light of the Agency's 1991 alpha_{2u}-globulin (α_{2u}-g) regulatory policy and the public comments received in response to the March, 1994 announcement. This notice provides the Agency's final decision, its response to comments, and the rationale for its final decision.

I. Introduction

Background information on pesticide registration and the Special Review process can be found in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.), and appropriate sections under 40 CFR part 154, published on November 27, 1985 (50 FR 49015). For a more comprehensive summary of the legal and regulatory background pertaining to lindane, refer to the Agency's proposed decision not to initiate a Special Review on rat kidney effects, published on March 18, 1994 (59 FR 12916). Below is a summary of the text of that document.

A. Background

Lindane (*gamma-hexachlorocyclohexane*) is a broad spectrum organochlorine insecticide/acaricide registered for control of insects and other invertebrates on a wide variety of sites. This pesticide is currently registered for use on field and vegetable crops (including seed treatments) and non-food crops (ornamental and tobacco), greenhouse food crops (vegetables), forestry (including Christmas trees), domestic outdoor and indoor (pets and household uses), commercial indoor (food/feed storage areas and containers), animal premises, wood or wooden structures, and human skin/clothing (military use only).

B. Regulatory History

Between 1977 and 1983, EPA conducted a Special Review that was based on the carcinogenicity, fetotoxicity/teratogenicity, and reproductive effects of lindane, and its potential to cause blood dyscrasia, as well as acute toxicity to aquatic wildlife. In the Agency's final determination (PD-4) published in 1983, the Agency canceled the indoor uses of smoke fumigation devices (by May, 1986) and the use of dips on dogs to control pests other than mites. Subsequently, the dog dip use was permitted for commercial use (kennel, farm, and sport dog uses only), provided that additional label

precautions were added to reduce applicator exposure. All other uses were allowed to continue with various restrictions. Those restrictions varied according to the degree of hazard associated with the use, but typical requirements included protective clothing, label statements describing necessary precautions, and restrictions of some products to certified pesticide applicators.

Following the conclusion of the Special Review in 1983, the Agency received a new 90-day subchronic rat feeding study which showed histopathological kidney and liver changes. Based on the effects observed in this study, on September 18, 1985, EPA notified registrants and applicants for registrations for lindane that the Agency was considering initiating a new Special Review base on concerns for workers exposed to lindane as a result of its forestry and uninhabited building uses.

The subchronic feeding study showed that lindane causes histopathological lesions, primarily in the kidney of male rats, and also in the liver of male and female rats. The kidney lesions were not completely reversed after a 6-week recovery period on a lindane-free diet. These renal changes included tubular degeneration, hyaline droplets, tubular casts, tubular distention, interstitial nephritis, and basophilic tubules. No adverse effects on kidney structure in female rats were noted. The liver effects (hepatocellular hypertrophy) were not regarded as a specific response to lindane because they are related to increased detoxification processes, and are considered a typical response and defensive mechanism to the presence of foreign substances.

Subsequent to the initial demonstration of lindane induced rat kidney lesions, the Agency required and received a number of additional toxicological studies aimed at elucidating the observed kidney effects. In summary, only male rats demonstrated the lindane induced kidney effects; while mice, rabbits and female rats did not. In the rat chronic feeding/carcinogenicity study, male Wistar rats demonstrated the characteristic α_{2u} -g kidney histopathological sequence of kidney lesions associated with increased "accumulation of hyaline droplets containing α_{2u} -g", "necrosis of tubule epithelium" leading to tubular degeneration, and subsequent formation of granular casts, without any evidence of lindane induced kidney tumors. (Refer to "Alpha_{2u}-Globulin: Association with Chemically Induced Renal Toxicity and Neoplasia in the Male Rat", Risk

Assessment Forum Monograph (EPA/625/391/019F, September 1991, page 2). The Monograph is available through the U.S. Government Printing Office: 1992-648-003/41809. A chemical analysis of the kidney for evidence of increased levels of α_{2u} -g revealed clear and pronounced compound dose-related increases in this protein. Furthermore, the exacerbation of hyaline droplets was due to the apparent binding of the α_{2u} -g to lindane as an adduct, which accumulates in the kidney proximal tubules and cannot be excreted (refer to Monograph, page 92). Lindane is one of a group of α_{2u} -g chemical inducers tested that has been shown to produce "the sequence of lesions characteristic of the α_{2u} -g syndrome" in the absence of renal tubule tumors in the male Wistar rat (refer to Monograph, page 89).

In the above Monograph, the Agency outlined its regulatory policy for human risk assessment for chemical agents that affect the male rat kidney through the α_{2u} -g mechanism (refer to Monograph, page 89). This policy states "if a compound induces alpha 2u-globulin accumulation in hyaline droplets, the associated nephropathy in male rats is not an appropriate endpoint to determine noncancer (systemic) effects potentially occurring in humans. Likewise, quantitative estimates of noncancer risk (e.g., reference doses and margin of exposure determinations) are based on other endpoints." In the case of lindane, the Agency has reviewed the weight-of-evidence in light of the 1991 α_{2u} -g policy, and has concluded that the observed renal effects were the result of the α_{2u} -g mechanism. The potential for lindane to induce kidney lesions in male rats is not currently regarded as being relevant to human health risk assessment. Therefore, the renal effects observed do not provide a basis for a Special Review of lindane.

II. Comments Received on the Proposed Notice Not to Initiate a Special Review on Kidney Effects

In its March, 1994 proposal not to initiate a Special Review, the Agency provided a 60-day comment period, which ended on May 17, 1994. EPA received five sets of comments, most of which were responses from public interest groups.

Comment. All of the commenters urged the Agency not to abandon the Special Review of lindane because there are additional health concerns beyond kidney effects that are currently not under consideration in the review by EPA.

Agency Response. In 1983, EPA concluded a major Special Review effort of lindane based on carcinogenicity,

fetotoxicity/teratogenicity, reproductive effects, and acute effects on aquatic organisms. This effort resulted in the cancellation of indoor uses of smoke fumigation devices and greatly limited the use of pet dips on dogs. In addition, there were uses that were allowed to continue only if certain imposed restrictions were implemented. The restrictions were based on the degree of associated hazards, and included changes in warning labels, the wearing of protective clothing, and restrictions to limit uses to certified pest control operators. Today's action only deals with the concerns originally raised in the 1985 preliminary notification to registrants and applicants of lindane, that is, kidney effects to workers exposed to lindane in forestry and uninhabited building uses. The Agency has concluded that the unique kidney effects induced via the α_{2u} -g mechanism in the rat have no direct biological relevance for human risk assessment. Consequently, there is no basis for initiating a Special Review of lindane due to the kidney effects at this time. However, the Agency recognizes that organochlorine pesticides, such as lindane, can cause endocrine disruption that may be associated with risk concerns. The Agency is currently developing a strategy to look at organochlorine pesticides as a group to examine their role as endocrine disruptors. Although the Agency is not initiating a Special Review on lindane for kidney effects, the findings from a comprehensive examination of the group of chemicals could lead to further regulatory action on lindane.

Comment. Several commenters pointed to concerns for breast cancer, neurotoxic, endocrine-disruption and other health effects from the continued use of lindane products. The commenters urged that EPA take more aggressive actions to further reduce risk.

Agency Response. The issues raised by the commenters were not Special Review triggers in the 1985 preliminary notification letter to registrants of lindane. Also, the identification of a possible toxic response or health concern to a given chemical does not always indicate that Special Review criteria have been exceeded. The recently completed rat carcinogenicity study did not demonstrate an association between lindane exposure and carcinogenicity. Presently, the Agency does not have a mouse carcinogenicity study that meets current acceptance criteria and a new study has been requested. However, the literature reports suggesting an apparent relationship between lindane and breast cancer in humans require further

evaluation. Investigation is underway at the National Cancer Institute to determine whether the association found in these studies can be confirmed. The possible endocrine effects reported in the literature to date have not been evident in those studies conducted in rats reviewed by the Agency, nor has immunotoxicity been indicated to be a critical endpoint for lindane toxicity. The Agency is considering additional data requirements for reregistration, including a neurotoxicity study, and the need for requiring special studies to assess both immunotoxicity and endocrine effects. The Agency is currently developing a strategy for examining the role of organochlorine chemicals as endocrine disrupters. Such an effort could result in the Agency pursuing further regulatory action against lindane. Today's action only deals with the kidney effects and does not preclude the Agency from taking future regulatory action against this chemical based on the risk concerns raised above.

Comment. Several commenters suggested EPA ban further use of lindane because the severity of the pesticide's environmental and health concerns have already caused regulators in more than a dozen countries to ban or severely restrict the use of this chemical.

Agency Response. EPA updates and reviews its scientific database on a routine basis for new evidence on chemicals which may identify risk concerns. Any regulatory action must meet the scrutiny of sound science and be consistent with the statutes and regulations governing pesticide registration and use. The Agency will exercise its authority to ban or restrict the use of pesticides when such action is necessary to protect against unreasonable adverse effects.

III. Reregistration Activities

EPA is considering what additional toxicological data are necessary to support continued registration, which include carcinogenicity and developmental neurotoxicity studies. Upon receipt and review of any of these studies, the Agency could initiate a Special Review or take other appropriate regulatory action if risk concerns are raised.

IV. Conclusion

Today's notice announces the Agency's final decision that the lindane induced kidney effects observed in male rats are not relevant for human risk assessment, nor do these effects meet the risk criteria for initiation of a Special Review. Because EPA no longer

believes there is a renal-related hazard posed to humans, the Agency will not initiate a Special Review for this effect. The Agency is developing a strategy to look at the role of organochlorine pesticides, such as lindane, may play as endocrine disrupters to better understand the risks from this group of chemicals. This action does not preclude the Agency from taking action on this chemical in the future as new information on this or any other risk concern becomes known.

Dated: July 19, 1995.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 95-18368 Filed 7-25-95; 8:45 am]

BILLING CODE 6560-50-F

[OPP-30390; FRL-4966-1]

Monterey Laboratories; Application to Register a Pesticide Product

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application to register a pesticide product involving a changed use pattern pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments must be submitted by August 25, 1995.

ADDRESSES: By mail, submit written comments identified by the document control number [OPP-30390] and the file symbol (63608-R) to: Public Response and Program Resources Branch, Field Operations Divisions (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Environmental Protection Agency, Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will be accepted on disks in Wordperfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-30390]. No "Confidential Business Information" (CBI) should be submitted through e-mail. Electronic comments on this notice may be filed online at many

Federal Depository Libraries. Additional information on electronic submission can be found below in this document.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. CS51B6, Westfield Building North Tower, 2800 Crystal Drive, Arlington, VA 22202, (703) 308-8097; e-mail: bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA received an application from Monterey Laboratories, 777 Maher Court, P.O. Box 189, Watsonville, CA 95077-0189, to register the pesticide product Vertigo Mushroom Fungicide (EPA File Symbol 63608-R), containing the active ingredient cinnamaldehyde at 50 percent, which involves a changed use pattern pursuant to the provisions of section 3(c)(4) of FIFRA. This product is for general use to include in its presently registered use, the control of larvae of soil dwelling beetles on or in turfgrass, landscape ornamentals, soil, transpiration facilities, and interior plantscapes. Notice of receipt of this application does not imply a decision by the Agency on the application.

Notice of approval or denial of an application to register a pesticide product will be announced in the **Federal Register**. The procedure for requesting data will be given in the **Federal Register** if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

A record has been established for this notice under docket number [OPP-