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ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/39]

ALDICARB

SPECIAL REVIEW OF PESTICIDE PRODUCTS CONTAINING ALDICARB

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Special Review.

SUMMARY: This Notice announces that EPA is initiating a Special Review of all pesticide products containing the active ingredient aldicarb [2-methyl-2-(methylthio)propionaldehyde-o-(methylcarbamoyl)oxime]. EPA has determined that aldicarb's use, which had led to contamination of ground water, may pose a substantial question of safety to man or the environment as described in 40 CFR 162.11(a)(6). Accordingly, a Special Review of aldicarb-containing products is appropriate to determine whether registration of these products should be permitted to continue and, if so, under what terms and conditions. During the Special Review process, EPA will seek to evaluate the adequacy of current or potential actions to limit ground water contamination by aldicarb.

DATE: Comments, evidence to rebut the presumptions in this Notice, and other relevant information must be received on or before (insert date 45 days after publication in the FEDERAL REGISTER).

ADDRESS: Written comments by mail to:

Information Services Section,
Program Management and Support Division (TS-757C),
Office of Pesticide Programs,
Environmental Protection Agency,
401 M St., SW.,
Washington, D.C. 20460

In person, bring comments to:

Rm. 236, CM#2,
1921 Jefferson Davis Highway,
Arlington, VA.

Information submitted in any 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 to the submitter. All written comments will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: By mail:

Michael F. Branagan,
Registration Division (TS-767C),
Office of Pesticide Programs,

Environmental Protection Agency,
401 M St., SW.,
Washington, D.C. 20460,
Office location and telephone number:
Rm 711-I, CM #2,
1921 Jefferson Davis Highway,
Arlington, VA,
(703-557-7420).

SUPPLEMENTARY INFORMATION: EPA has determined that a Special Review will be conducted for all pesticide products containing aldicarb. The term "Special Review" is the name now being used by EPA for the process previously called the Rebuttable Presumption Against Registration (RPAR) process. This name and associated modifications in the process will be proposed in regulations in the near future. Until other applicable final regulations are adopted, the present Special Review will adhere to RPAR procedures now in effect and set forth in 40 CFR 162.11(a).

Issuance of this Notice (also called Position Document 1 [PD1]) means that potential adverse effects associated with the use of aldicarb have been identified and will be examined further to determine their extent and whether, in light of the benefits of aldicarb, such risks are unreasonable.

A document entitled "Requirements for Interim Registration of Pesticide Products Containing Aldicarb" has been issued and is available to the public from the above-identified contact person. That document explains the basis of EPA's

decision to start this Special Review and also contains references, background information, data requirements, and other information pertinent to the interim continued reregistration of pesticides containing aldicarb.

Finally, a meeting of the FIFRA Scientific Advisory Panel (SAP) was held between June 12 and June 14, 1984 to discuss, among other things, EPA's concerns about ground water contamination by aldicarb. The comments of the SAP, the registrant and the public will be addressed in the Special Review.

I. INITIATION OF A SPECIAL REVIEW

A. GENERAL

Issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (7 U.S.C 136-136y), 40 CFR 162.11 provides that an RPAR (Special Review) shall be conducted if EPA determines that a pesticide meets or exceeds any of the risk criteria relating to the safe use of a pesticide set forth in 40 CFR 162.11(a)(6)(i). A Special Review under that section is also appropriate when it appears that evidence available to the Administrator indicates that a pesticide poses a substantial question of safety to man or the environment. In making the determination to initiate a Special Review, EPA is guided by section 3(c)(8) of FIFRA which directs EPA to begin an RPAR (Special Review) only if it is based on a "validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or the environment." If such a determination is made, the

registrant(s) will be notified by certified mail and afforded an opportunity to submit evidence in rebuttal to EPA's presumption. Registrants have been sent, by certified mail, copies of document entitled "Requirements for Interim Registration of Pesticide Products Containing Aldicarb." In addition, any registrant may voluntarily petition EPA to cancel the registration of its product(s).

Following the initiation of the Special Review, the pesticide use or uses of concern will enter the public discussions stage of the Special Review process. Registrants and interested members of the public may discuss the Agency's proposed actions and/or other proposals for additional or alternative actions. Specifically, registrants must submit information indicating that aldicarb does not pose a health risk to man or the environment and/or that the benefits exceed the risks associated with aldicarb use. Interested members of the public may submit information concerning the risks and benefits associated with the use of aldicarb. Requests for all meetings for these purposes should be made in accordance with directions described in Unit V, below.

If risk issues cannot be fully resolved during the public comment period, EPA will proceed to evaluate the risks and benefits of aldicarb and to propose a regulatory solution in a Position Document 2/3 (PD 2/3). After obtaining comments from the Scientific Advisory Panel, the Secretary of Agriculture, registrants, and the public on PD 2/3, EPA would issue a Position Document 4 (PD 4) containing EPA's final regulatory position. If EPA determines that the risks of use exceed the

benefits, EPA would issue a notice of intent to cancel the registration of products intended for such use. The notice may identify for specific uses certain changes in the composition, packaging, application methods and/or labeling of the product which would reduce the risks to levels that EPA would consider acceptable. Cancellation would become effective unless, within 30 days of issuance of the notice, the registrant either requests a hearing to challenge the cancellation or submits an application to amend the product's registration in a manner prescribed in the notice of intent to cancel.

It is emphasized that a Notice initiating a Special Review is not a notice of intent to cancel the registration of a pesticide, and a Special Review may or may not lead to cancellation. Rather, such a Notice is an announcement of EPA's concern about the safe use of a pesticide and, only after carefully considering the risks and benefits of a pesticide and determining that the pesticide would cause unreasonable adverse effects on the environment, would EPA issue a notice of intent to cancel. Commenters may also submit, for consideration, data on benefits which they believe are relevant to registration or continued registration of products containing aldicarb.

B. PRESUMPTION

EPA has determined that use of pesticide products containing aldicarb may meet or exceed the risk criteria in 40 CFR 162.11(a)(6)(i). That section provides that a Notice of Intent to cancel a pesticide may be issued if "... based on toxicological data, epidemiological studies, use history,

accident data, monitoring data, or such other evidence as is available to the Administrator, the pesticide may pose a substantial question of safety to man or the environment..." Aldicarb has an extremely high acute oral toxicity; however, based on a fairly complete range of test results, aldicarb does not cause adverse chronic health effects. Aldicarb has been found in ground water in a large number of States.

On the basis of the scientific studies and information summarized in this PDI, EPA has concluded that aldicarb and its two degradation products of toxicological concern, aldicarb sulfoxide and aldicarb sulfone, are mobile in soil. These chemicals also persist longer in soil under anaerobic conditions (generally greater than 2 to 3 feet underground) than under aerobic soil conditions (at depths from zero to 2 to 3 feet underground). Aldicarb residues have been found in water from wells near treated fields at concentrations ranging from 10 to 200 ppb, levels which exceed the health advisory level of 10 ppb (HAL) established by the Office of Drinking Water (ODW) of EPA, in the following states: Californial, Maine, Massachusetts, Missouri, New Jersey, New York, Wisconsin, Virginia. Levels up to 500 ppb have been found in New York. Concentrations between 1 to 10 ppb have been found in the following States: Arizona, Connecticut, Florida, Washington, South Carolina, Texas, North Carolina, and possibly other States. Because aldicarb residues have half-lives as long as several years, under conditions typically found in ground water, the time required for degradation of aldicarb ground water residues to non-toxic compounds will be long.

The Office of Pesticide Programs (OPP) currently estimates a Theoretical Maximum Residue Contribution (TMRC) to the daily diet for aldicarb and its metabolites of 0.1120 mg/dy from residues of aldicarb in or on raw agricultural commodities resulting from treatment with aldicarb. The TMRC estimate is a maximum dietary exposure to a pesticide approved for use on a specific set of agricultural commodities. In preparing its TMRC estimate, EPA assumed that each individual consumes a 1.5 kg daily diet consisting of typical amounts of the agricultural commodities containing the maximum residues (or tolerances) of the pesticide and its metabolites permissible under 40 CFR 180.269. The TMRC utilizes 62 percent of the Allowable Daily Intake (ADI) for aldicarb of 0.003 mg/kg/dy.

The ADI for aldicarb and its metabolites has undergone extensive critical review within the last few years. ODW has used a proposed ADI of 0.001 mg/kg/dy, based on recommendations of the National Academy of Sciences Safe Drinking Water Committee in 1977 and 1983 to derive its HAL. More recently, EPA's Environmental Criteria and Drinking Water Office (Cincinnati) prepared a preliminary toxicological analysis of aldicarb proposing an ADI of 0.0012 mg/kg/dy. In 1982, the World Health Organization re-evaluated the ADI for aldicarb and recommended a value ranging from 0 to 0.005 mg/kg/dy. Additionally, a report issued by the Institute for Comparative and Environmental Toxicology at Cornell University in 1983, suggested "a reasonable range for the ADI to be 0.003 to 0.01 mg/kg/dy, the OPP currently accepted value of 0.003 mg/kg/dy being the most

conservative and the upper value of .01 mg/kg/dy being a dose that causes a depression of whole blood cholinesterase approximating the range of normal intra-individual variation." OPP considers it prudent, at this time, not to alter its established ADI of 0.003 mg/kg/dy.

In light of the extent to which permissible residues of aldicarb are found in foodstuffs, consumption of contaminated ground water presents an additional source of dietary exposure which must be carefully considered by the Agency.

In response to the current ground water contamination situation, Union Carbide Corporation, the sole registrant for technical aldicarb has installed activated carbon water filtration units on wells on Long Island which contain aldicarb residues above 7 ppb. The current label for aldicarb includes geographical and temporal restrictions which are thought to reduce the likelihood of drinking water contamination. Utilizing information from past, present and future studies of ground water contamination, the Special Review will consider the utility, practicality and enforceability of these and other labeling restrictions that would permit the continued use of aldicarb, while preventing unreasonable adverse effects on the environment from ground water contamination with aldicarb and its degradation products.

In conducting this Special Review, the Agency will consult State and Local agencies responsible for maintenance and protection of underground drinking water sources in an effort to assess the impact of further aldicarb contamination on their responsibilities. In conjunction with the Agency's

broader initiatives on ground water contamination, OPP will consult with the ODW and the newly created Office of Groundwater Protection (OGP) during the Special Review. ODW is also conducting a review of aldicarb as a potential candidate for regulation. ODW, OGP and OPP will work together during their respective reviews to assure resolution of potential differences in approaches and for development of consensus on any issues. The Agency will consider the results of an ongoing comprehensive assessment of the environmental fate and potential health impacts of the nematicide uses of aldicarb on Florida citrus. This assessment is expected to be completed in early 1985. Finally, the Agency has an application for a pesticide, called aldoxycarb, that has toxicity characteristics, potential for ground water contamination and use sites which are similar to aldicarb. Aldoxycarb is a metabolite of aldicarb. The Agency will consider the toxicity of aldoxycarb and its ability to reach ground water resources when used as an active ingredient. The Agency will use the conclusions of this Special Review in making its decision on the pending application for aldoxycarb registration.

C. REBUTTAL CRITERIA

All registrants, applicants for registration, and other interested members of the public are invited to submit evidence either to support or to rebut the presumption (as listed in Unit I.B. of this Notice) that the use of aldicarb products may cause adverse health effects via ground water contamination.

D. BENEFITS INFORMATION

The Agency will perform a benefits analysis for aldicarb during Special Review. The following information briefly summarizes the market status of aldicarb.

Union Carbide is the sole manufacturer of technical aldicarb and estimates of domestic production are considered as trade secret or proprietary under sections 7(d) and 10 of FIFRA. Aldicarb, an insecticide/nematicide registered for use on a variety of sites, is used primarily on cotton, potatoes, peanuts, soybeans and pecans, with these five sites comprising approximately 90 percent of annual usage of aldicarb. Minor usage sites include ornamentals, sugar beets, citrus, sugar cane, sorghum, edible beans and sweet potatoes.

In addition to submitting evidence to rebut the presumption of risk in the Special Review, 40 CFR 162.11(a)(5)(iii) provides that a registrant or applicant " may submit evidence as to whether the economic, social and environmental benefits of the use of the pesticide subject to the presumption outweigh the risk of use." If the presumption of risk is not rebutted, the benefits evidence submitted by registrants, applicants, and other interested persons will be considered by the Administrator when determining the appropriate regulatory action.

Registrants, applicants, or other interested persons who desire to submit benefits information should consider submitting information on the following subjects along with any other relevant information they desire to submit:

1. Identification of the economically important uses of aldicarb, including market studies and estimated quantities applied for those uses.

2. Identification of alternative chemical and non-chemical methods for all registered uses and application techniques, including any associated health effects and potential for ground water contamination.

3. Determination of the change in costs to aldicarb users of obtaining equivalent pest control with available substitute products or management techniques.

4. Assessment of the expected changes in level of pest damage (if any) and environmental impacts associated with the use of alternative control measures.

5. Assessment of the long term effects (health, decontamination costs, etc.) of continued aldicarb use.

II. ADDITIONAL GROUNDS FOR REVIEW

In addition, EPA is requiring, pursuant to section 3(c)(2)(B) of FIFRA, that additional testing of the toxicological, ecological and environmental fate properties of aldicarb be conducted. Upon receipt of these studies, they will be reviewed to determine the extent to which other adverse effects may be associated with the use of this chemical. EPA expects to receive toxicological studies by April, 1985, and ecological and environmental studies by April, 1986.

III. REBUTTAL SUBMISSION PROCEDURES

All registrants and applicants for registration are being notified by certified mail of the Special Review that is being initiated on their products containing aldicarb.

The registrants and applicants for registration will have 45 days from the date this notice is received or until (insert date 45 days after publication in the FEDERAL REGISTER) (whichever is later) to submit evidence in the rebuttal to EPA's presumption. Other interested persons may submit comments during the same period. EPA is interested in a prompt resolution of this Special Review and therefore will not grant an extension of the comment period unless good cause is shown.

IV. DUTY TO SUBMIT INFORMATION ON ADVERSE EFFECTS

Registrants are required by law to submit to EPA any additional information regarding unreasonable adverse effects on man or the environment which comes to their attention at any time, pursuant to section 6(a)(2) of FIFRA. Registrants of aldicarb products must immediately submit any published or unpublished information, studies, reports, analyses, or reanalyses regarding ground water contamination, any aldicarb effects in animal species or humans, and claimed or verified accidents to humans, domestic animals, or wildlife which have not been previously submitted to EPA. These data must be submitted with a cover letter specifically identifying the information as being submitted under section 6(a)(2) of FIFRA. Registrants should notify EPA of any studies on

aldicarb currently in progress, their purpose, the protocol, the approximate completion date, and a summary of all results observed to-date.

V. PUBLIC COMMENTS, INSPECTIONS AND REQUESTS FOR MEETINGS

During the time allowed for submission of rebuttal evidence, specific comments on the presumptions set forth in this Notice and on the material in the Guidance Document for interim registration are solicited from the public. In particular, any documented episodes of adverse effects on humans or domestic animals should be submitted to EPA as soon as possible. Any information as to any laboratory studies in progress or completed should be submitted to EPA as soon as possible with a statement as to whether those studies are in compliance with the Good Laboratory Practicies specified in 48 FR 53946. Specifically, information on any adverse effects from ground water contamination or ways to reduce ground water contamination through labeling or other means is solicited. Similarly, submission of any studies or comments on the benefits from the use of aldicarb is requested. All comments and information and analysis thereof, which come to the attention of EPA, may serve as a basis for final determination of regulatory position following the Special Review.

All comments and information should be sent to the address given above, preferrably in triplicate, to facilitate the work of EPA and others interested in inspecting them. The comments and information should bear the identifying notation [OPP-30000/39].

During the rebuttal comment period, interested members of the public or registrants may request a meeting to discuss the risk issues, methods of reducing risks, or other relevant matters. Requests for such meetings should be directed to the contact person listed in this Notice. Any records pertaining to such meetings, including minutes, agendas, and comments received, will be filed under docket number "OPP-30000/39".

Date: 6/28/84

Steven Schatzow, Director
Office of Pesticide Programs

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15. Supplementary Notes

16. Abstract (Limit: 200 words)

This Position Document addresses the risks and benefits of pesticide products containing the subject active ingredient. The Agency has determined that the use of products containing the subject active ingredient may meet or exceed a risk criterion described in 40 CFR Part 154. Potential hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of the subject active ingredient, whether such risks cause unreasonable adverse effects on the environment.

17. Document Analysis a. Descriptors

PESTICIDES, STANDARDS, REGULATIONS, MANUFACTURING, CHEMISTRY, TOXICOLOGY, RESIDUES, ECOLOGY, PATH OF POLLUTANTS

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