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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

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Department of Commerce

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000-8B]

PESTICIDE PRODUCTS CONTAINING FLUOROACETAMIDE (COMPOUND 1081)

NOTICE OF DETERMINATION CONCERNING THE REBUTTABLE PRESUMPTION AGAINST REGISTRATION

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Determination and Availability of Position Document Concerning Fluoroacetamide (Compound 1081).

SUMMARY: This notice announces the termination of the rebuttable presumption against registration (RPAR) of pesticide products containing Fluoroacetamide (Compound 1081), pursuant to 40 CFR 162.11(a)(5)(i), and states the reasons for terminating the RPAR.

DATE: Effective (insert date of publication in the FEDERAL REGISTER).

FOR FURTHER INFORMATION CONTACT:

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Phone (703) 557-7400.

SUPPLEMENTARY INFORMATION:

I. INTRODUCTION

On December 1, 1976, the Environmental Protection Agency issued a notice of rebuttable presumption against registration and continued registration (RPAR) of pesticide products containing Fluoroacetamide (Compound 1081) published in the FEDERAL REGISTER of December 1, 1976 (41 FR 52792), a compound currently registered in the United States as a rodenticide, and thereby initiated the Agency's public review of the risks of Compound 1081. This notice constitutes the Agency's Notice of Determination pursuant to 40 CFR 162.11(a)(5)(i), terminating the Compound 1081 RPAR.

The presumption against Compound 1081 was based on lack of emergency treatment, acute toxicity to mammalian and avian species, and significant reduction of non-target populations and fatalities to members of endangered species. The risk information submitted in response to the RPAR notice did not satisfy the Agency's risk concerns. At the time the rebuttable presumption against registration was issued, two registrants held registrations for Compound 1081 pesticide products. In 1978, the holder of one registration requested a voluntary cancellation.

Thereafter, the sole remaining registrant of Compound 1081 products voluntarily agreed to modifications in the terms and conditions of registration, which have the result of substantially reducing the risks posed by Compound 1081. Since label amendments regarding use restrictions and modified use directions have been proposed and accepted, the likelihood of exposure to humans, non-target mammals, birds, and endangered species is very remote. Accordingly, the Agency has concluded that the presumption against Compound 1081 has been rebutted.

II. LEGAL BACKGROUND

In order to obtain a registration for a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), a manufacturer must demonstrate that the pesticide statisfies the statutory standard for registration. That standard requires, among other things, that the pesticide perform its intended function without causing "unreasonable adverse effects" on the environment (section 3(c)(5)). "Unreasonable adverse effects on the environment" are defined to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide (section 2(bb)). In effect, this standard

requires a finding that the benefits of any use of the pesticide exceed the risks of that use when the pesticide is used in accordance with commonly recognized practice. The burden of proving that a pesticide satisfies the registration standard continues as long as the registration remains in effect. Under section 6 of FIFRA, the Administrator is required to cancel the registration of a pesticide or modify the terms and conditions of registration whenever he determines that the pesticide no longer satisfies the statutory standard for registration.[1/]

The Agency created the RPAR process to facilitate the identification of pesticide uses which may not satisfy

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1/ Another part of the statutory standard for registration is that the pesticide must satisfy the labeling requirements of FIFRA. These requirements are set out in the statutory definition of "misbranded" (FIFRA Section 2(q)). Among other things, this section provides that a pesticide is misbranded if: "the labeling . . . does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any . . . (restrictions), imposed under Section 3(d) . . . are adequate to protect health and the environment.

The Agency can require changes to the directions for use of a pesticide in most circumstances either by finding that the pesticide is misbranded if the label is not changed, or by finding that the pesticide would cause unreasonable adverse effects on the environment, unless labeling changes are made which accomplish risk reductions.

the statutory standard for registration and to provide a public, informal procedure for gathering and evaluating information about the risks and benefits of these uses.

The regulations governing the RPAR process are set forth in 40 CFR 162.11. This section provides that a rebuttable presumption shall arise if a pesticide meets or exceeds any of the risk criteria set out in the regulations. The Agency announces that an RPAR has arisen by publishing a notice in the Federal Register. After an RPAR is issued, registrants and other interested persons are invited to review that data upon which the presumption is based and to submit data and information to rebut the presumption. Respondents may rebut the presumption of risk by showing that the Agency's initial determination of risk was in error or by showing that use of the pesticide is not likely to result in any significant exposure to humans, or to animals or plants of concern with

regard to the adverse effect in question.[2/] Further, in addition to submitting evidence to rebut the risk presumption, respondents may submit evidence as to whether the economic, social and environmental benefits of the use of the pesticide subject to the presumption outweigh the risks of use.

2/ 40 CFR 162.11(a)(4) provides that registrants and applicants may rebut a presumption against registration by sustaining the burden of proving:

> "(i) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraphs (a)(3)(i) or (iii) that when considered with the formulation, packaging, method of use, and proposed restrictions on and directions for use and widespread and commonly recognized practices of use, the anticipated exposure to an applicator or user and to local, regional or national populations of non-target organisms is not likely to result in any significant acute adverse effects; or (ii) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraph (a)(3)(ii) that when considered with proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist or accrue to levels in man or the environment likely to result in any significant chronic adverse effects; or (iii) that the determination by the Agency that the pesticide meets or exceeds any of the criteria for risk was in error."

A primary purpose of the RPAR process is to screen for appropriate action those pesticide uses which pose risks which are of sufficient concern to require the Agency to consider whether offsetting benefits justify the risks. Accordingly, the Agency's approach to rebuttal determinations concentrates on whether the risk concerns which are central to each RPAR proceeding have in fact been answered.

The regulations require the Agency to conclude an RPAR by issuing a Notice of Determination in which the Agency states and explains its position on the question of whether the risk presumptions have been rebutted. If the Agency determines that the presumption has been rebutted, the Agency will not perform a detailed analysis of the benefits of the use of the pesticide. Where the risk trigger has been rebutted, such a benefits analysis is unnecessary to support a conclusion that the pesticide does not appear to pose unreasonable adverse effects on the environment. A conclusion that the presumption has been rebutted results in the termination of the RPAR process. The Agency will either approve a pending registration application or permit the registration of the pesticide to continue without modification in the terms and conditions of registration. 40 CFR 162.11(a)(5)(i).

In the event the presumptions are not rebutted, the Agency will consider information relating to the social, economic, and environmental costs and benefits of the pesticide. If the Administrator determines, after weighing risks against benefits, that regulatory measures are necessary to prevent unreasonable adverse effects on the

environment under section 6(b) or 3(c)(6), he may propose risk reduction measures ranging from modifications in the terms and conditions of registration to cancellation or denial of registration.

FIFRA requires the Agency to submit cancellation notices issued pursuant to section 6 to the Scientific Advisory Panel for review and comment on the health and environmental aspects of the proposed decision and to the Secretary of Agriculture for comments on the impact of the proposed decision on the agricultural economy. However, the Agency is not required to submit a decision not to initiate cancellation proceedings against a pesticide after RPAR review to either the Scientific Advisory Panel or the Secretary of Agriculture for review and comment. Hence, the Agency has no statutory obligation to refer a decision to terminate an RPAR for external review.

III. DETERMINATION THAT THE REBUTTABLE PRESUMPTION HAS BEEN REBUTTED

The Agency has considered information on the risks associated with the uses of Fluoroacetamide (Compound 1081) including information submitted by registrants and other interested persons in rebuttal to the Fluoroacetamide RPAR. The Agency's assessment of the risks associated with

the use of Compound 1081 and its conclusions regarding whether the use of Compound 1081 under current label restrictions poses unreasonable adverse effects are set forth in the Position Document accompanying this Notice. The Position Document is hereby adopted by the Agency as its statement of reasons for the determination announced in this Notice. For the reasons summarized below and developed in detail in the Position Document, the determination of the Agency with respect to Compound 1081 is as follows:

a. Determination on risks. The Compound 1081 RPAR was based on information indicating that Compound 1081 posed the following risks to humans and the environment: lack of emergency treatment; acute toxicity to mammalian and avian species; and significant reduction to non-target populations and fatalities to members of endangered species.

As developed more fully in the Position Document, the Agency has determined that the presumption against Compound 1081 has been rebutted. The sole remaining registrant voluntarily proposed that certain restrictions and modified directions for use be incorporated on the label. The proposed label was approved on November 2,

1979. With these revisions, the risks cited in the presumption no longer appear to be of concern, because anticipated exposure to Compound 1081 would be insignificant and would be unlikely to result in any significant acute or chronic adverse effects in humans and on the environment.

b. Determination on benefits. Under the revised label, Compound 1081 is registered for use in sewers for killing Norway rats and roof rats. The Agency did not perform a detailed analysis of the economic benefits for this use, because the Agency determined that the pesticide does not pose any appreciable risk under the current label.

c. Determination of unreasonable adverse effects. For the reasons set forth in detail in the accompanying Position Document, the Agency has determined that the current use patterns of Compound 1081 do not pose unreasonable adverse effects to humans or the environment. Accordingly, the registration of Compound 1081, as voluntarily modified, will be allowed to continue in effect without further modification in the terms and conditions of registration.

IV. PROCEDURAL MATTERS

As indicated above, this Notice of Determination announces the termination of the notice of rebuttable presumption against registration of pesticide products containing Fluoroacetamide (Compound 1081).

Interested persons may obtain copies of the Position Document by contacting Tim Gardner, Office of Pesticide Programs, Special Pesticide Review Division, EPA (TS-791), Room 711-C, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202, (703) 557-7400.

Dated: 2/19/80

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Assistant Administrator
Toxic Substances