

Exemption of Certain Pesticide Substances From Federal
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[OPP-300350A; FRL 4984-8]

RIN 2070-AC67

Exemption of Certain Pesticide Substances From Federal Insecticide, Fungicide, and Rodenticide Act Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule establishes an exemption from regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for certain pesticides. EPA has determined that these pesticides, under certain conditions, are of a character not necessary to be regulated under FIFRA in order to carry out the purposes of the Act. EPA has concluded that exemption of products covered by this final rule will not pose unreasonable risks to public health or the environment and will, at the same time, relieve producers of the burden associated with regulation. Pesticidal products that do not meet the conditions of this final rule will continue to be regulated under FIFRA. **DATES:** This rule becomes effective May 6, 1996.

FOR FURTHER INFORMATION CONTACT: Robert S. Brennis, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. Office location: Room 713, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. Telephone: 703-305-7501, e-mail: brennis.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Authority: This rule is issued under the authority of FIFRA section 25(b).

EPA issued a proposed rule in the Federal Register on September 15, 1994 to exempt from FIFRA regulation certain pesticidal substances (59 FR 47289). In its proposal, EPA identified a total of 31 pesticidal active ingredients that it believed were not of a character necessary to be regulated under FIFRA.

In developing its list of exempted substances, EPA applied certain factors. Consideration was given to such factors as, (1) whether the pesticidal substance is widely available to the general public for other uses; (2) if it is a common food or constituent of a common food; (3) if it has a nontoxic mode of action; (4) if it is recognized by the Food and Drug Administration (FDA) as safe; (5) if there is no information showing significant adverse effects; (6) if its use pattern will result in significant exposure, and (7) if it is likely to be persistent in the environment.

EPA also proposed, as a condition of exempted status, several restrictions. First, the proposal identified active ingredients and listed certain inert ingredients that would be permitted in exempted formulations. Pesticide formulations would qualify only if all of the ingredients contained in the product were exempt. All inert ingredients contained in the formulation would have to be from the list of inerts identified as minimum risk inerts as published in the Federal Register as List 4A inerts. This list was last published in the Federal Register, September 28, 1994 (59 FR 49400). Second, in order to qualify for the exemption, the pesticide product label must identify all the ingredients of the product. Third, labels must comply with established regulations regarding false and misleading statements (40 CFR 156.10(a)(5)(i) through (viii)). And fourth, the substance or product could not bear claims either to control or mitigate microorganisms that pose a threat to human health or carriers of such microorganisms.

In its proposal, EPA solicited comments on the list of substances themselves, the evaluation factors and the conditions of exemption. EPA has determined, with the conditions imposed by this rule, that use of these pesticides poses insignificant risks to human health or the environment in order to carry out the purposes of the Act, and the

burden imposed by regulation is, therefore, not justified. The Agency, in promulgating this rule, is responding to society's increasing demand for more natural and benign methods of pest control, and to the desire to reduce governmental regulations and ease the burden on the public. The regulatory steps required to register any pesticide substance are formidable, not only for the Agency but for the applicants, who often are small businesses. The novice registrant often requires extra attention and instruction. EPA believes that both the applicant and the Agency are consuming valuable time, energy, and money to register chemicals that pose such low risk.

II. Implementation

Products registered with EPA which now qualify for exemption from pesticide regulation under this rule, will remain registered until further action is taken by the registrant. The Agency encourages voluntary cancellation of these registrations. Cancellation requests should be mailed to James A. Hollins, Office of Pesticide Programs (7502C) EPA, 401 M St., SW., Washington, DC 20460. The letter should request cancellation under FIFRA section 25(b) and specify the product to be canceled by both name and EPA registration number. Existing stocks may be distributed for 1 year after the date of cancellation. After that date, it will be a violation of FIFRA for the former registrant to sell or distribute stock with an EPA registration number displayed on the label. Products in channels of trade may be sold and used until supplies are exhausted.

Producers of products that are exempted from regulation by this final rule, will not be obligated to comply with the established registration and reporting requirements of FIFRA, section 7 with respect to exempted products. Producers who wish to market exempted products do not need to notify the Agency or obtain confirmation that the product is exempt. Provided the producer complies with all conditions of this rule, product may be distributed. To comply, producers must refer to this rule, the most recently published 4A inerts list, and a copy of the false and misleading labeling requirements contained in 40 CFR 156.10(a)(5)(i) through (viii). It is important to note that this rule only affects Federal regulation of pesticide products. Pesticide producers of exempt products should contact the pesticide agency in each State in which [Page 8877] they wish to market their products, to determine if there are State requirements which need to be met.

III. Public Comment and Agency Response

Fifty-six commenters responded to the proposed rule. Of these, 29 (52) generally opposed the proposal, and 23 (41) generally supported it. Fourteen of the 29 commenters who opposed the rule as proposed, expressed support for some form of reduced regulation of low-risk pesticides.

Supporters of the proposal include the "organic" industry, Greenpeace and companies likely to benefit from deregulation of these substances. Those opposed to the proposal include the States' FIFRA Issues Research Evaluation Group (SFIREG); State lead agencies with pesticide enforcement responsibilities in Arizona, California, New Jersey and Vermont; the Armed Forces Pest Management Board; the U.S. Department of Health and Human Services' Center for Disease Control; the National Coalition Against the Misuse of Pesticides (NCAMP); mosquito and vector control agencies; and several members of the regulated pesticide industry.

The supporters of the proposal generally agreed with EPA that regulation of the listed substances is not necessary to prevent unreasonable adverse effects on human health or the environment. Many commented that deregulation would encourage the development and use of "safer" pesticides and that the exemptions would benefit business, especially small business and the organic industry. Many supporters felt that EPA should more fully implement the proposal by greatly expanding the lists of exempted active ingredients and permitted inerts. Approximately 80 additional active ingredients and 50 inerts were proposed for future consideration. The Agency will evaluate each active ingredient and will include those it feels qualify for exemption in its next proposal. The inerts are presently being reviewed for possible inclusion in the next published list of inerts of minimum concern (inerts 4A list).

Among objections to the proposal, the most often repeated concern was that deregulation would result in a proliferation of ineffective products making false or misleading claims about product performance and/or safety and that the public would pay the price for inadequate oversight by EPA and the Federal Trade Commission (FTC). SFIREG, the State Lead Agencies, and others expressed concern that deregulation would create a number of serious enforcement problems for States. Other significant concerns included the fear that deregulation of arthropod repellents would adversely affect public health; that certain substances proposed for exemption or included on the

list of permitted inerts were not "safe" or could cause adverse effects when used in combination or in ways not anticipated by EPA; that EPA's factors and process for determining which substances to exempt or its process for revoking exemptions in the face of reported adverse effects were inadequate; and that deregulation of these substances would give an unfair competitive advantage to manufacturers of exempt pesticide products. Although more than 50 percent of the commenters opposed the proposed exemptions, nearly half (14 of 29) of the opponents expressed support for some form of reduced regulation of low-risk pesticides. In response to concerns regarding labeling and enforcement, the Agency has changed the rule to provide specific label requirements as indicated in the following section of this rule. If these conditions are not met by products being distributed, then the conditions for exemption from regulation have not been met, and the Agency retains authority to bring enforcement action under FIFRA. It is significant to point out, that since one condition for exemption is that the product label cannot make false or misleading claims, it is important for formulators and distributors of unregulated products to ensure that they are not making any unsupported efficacy claims for any pest, particularly for those which may be of a possible public health concern.

The final rule clearly and concisely states which conditions manufacturers must meet to obtain exempted status for certain low-risk pesticides. States need only review whether a product meets those conditions to determine exempt status. The Agency is convinced that the deregulation of low risk products is wise. Exempted products should not require significant monitoring and it will not be difficult for States to identify properly exempted products. Those States which do not allow exemptions from State registration are free to continue to enforce their State provisions. Many commenters expressed concern that deregulation of some pesticides would give a competitive advantage to manufacturers of deregulated products. EPA's regulatory authority under FIFRA is primarily a licensing authority and every decision has some potential effect on competitors. The Agency does not consider potential impact on competitors to be a valid and sufficient reason to preclude an exemption under FIFRA.

While no one submitted compelling evidence that the listed substances should not be exempted from regulation, several people took issue with the way EPA approached exempting pesticides in general and expressed concerns about the specific factors the Agency used to arrive at its selections. The Agency agrees that any one factor, taken alone, is insufficient to make a minimum risk determination. Admittedly, many chemicals that are available to the public on a daily basis, pose some level of risk, and several higher-risk pesticides were once listed on FDA's Generally Recognized As Safe (GRAS) list. It is important to stress that these factors were not applied exclusive of one another, but rather in conjunction with all of the others. Moreover, the factors themselves are not meant to be absolute criteria and certainly some factors are unsupported for some of the substances. But, taken as a whole, EPA believes that the factors applied to each of the substances indicate that the substances will not pose a risk that warrants regulation under FIFRA. EPA researched each substance prior to proposing it for exemption. A general literature search was performed in addition to an in-house search of the Agency's own data base. In its proposal, the Agency invited the public to add to the list of factors or submit information that might be appropriate to consider in determining whether a substance should be exempted from FIFRA regulation. No information was submitted by commenters about the proposed pesticides to support their comments. Any person may submit evidence that refutes the Agency's conclusions that any exempted pesticide should no longer be exempted because of newly uncovered risk. EPA will consider such information in determining whether the exemption should be continued.

Commenters indicated that EPA should adopt a position similar to FDA's that allows cosmetics manufacturers to use the generic term "fragrance" on their labels. The requirement to list all ingredients on the exempted product label presents problems, since fragrances are often purchased from independent vendors, and their formulations are proprietary. Fragrances can be skin sensitizers or have other adverse effects, particularly at higher concentrations. The Agency's evaluation of fragrances is concentration dependent; that is, it is based upon the amount of fragrance that will be used in a given formulation. What is acceptable at 0.1 concentration, may not be acceptable at 2% concentration. In deregulating, the Agency would not be able to regulate the concentration of these fragrances in a formulation. The Agency understands the proprietary nature of many fragrance formulations, and we have evaluated ways of including fragrances on inerts list 4A. The Agency has found no workable solutions for this issue. The rule has not been changed.

All public comments and more detailed responses to specific issues, are available in the public docket.

IV. Revisions Made to the Rule in Response to Comments

The Agency has made the following changes from the proposed rule in response to the comments it received.

1. The ingredients cinnamon, citronella, garlic, and sesame have been revised to include their oils.
2. The requirement that the product label must indicate the percentage (by weight) of active ingredient(s) contained in the product has been added.
3. The requirement, "The substance or product must not bear claims either to control or mitigate microorganisms that pose a threat to human health or carriers of such microorganisms", has been amended to read, "The substance or product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including, but not limited to disease transmitting bacteria or viruses, or claims to control insects or rodents carrying specific diseases, including, but not limited to ticks that carry Lyme disease."
4. The requirement that products must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10(a)(5)(i) - (viii) has been added.

V. Public Docket

EPA has established a public docket for this rulemaking (OPP-300350 and 300350A). All comments received in response to the proposed and final rule are available in the public docket. A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4 p.m, Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Please address all written inquiries to the Public Response Section, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

VI. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), it has been determined that this rule is not "significant" and is therefore not subject to review by the Office of Management and Budget.

B. Regulatory Flexibility Act

This rule has been reviewed under the Regulatory Flexibility Act of 1980 (Pub.L. 96-354; 94 Stat. 1164, 5 U.S.C. 601 et seq.). EPA has determined that this rule will have a positive economic impact on a substantial number of small businesses which will no longer be subject to FIFRA regulation, thereby reducing their costs and regulatory burdens.

Accordingly, I certify that this rule does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

C. Paperwork Reduction Act

This rule contains no information collection requirements. Therefore, the Paperwork Reduction Act is not applicable.

D. SAP, USDA and Congressional Review

In accordance with FIFRA section 25, the FIFRA Scientific Advisory Panel (SAP) has waived review of this rule. A copy of the rule has been forwarded to the U.S. Department of Agriculture before publication. Copies of the final rule also were forwarded to the Committee of Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition and Forestry of the Senate.
List of Subjects in 40 CFR Part 152

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and record keeping requirements.

Dated: February 28, 1996.

Carol M. Browner,
Administrator.

Therefore, 40 CFR chapter I, part 152 is amended as follows:

PART 152--[AMENDED]

1. The authority citation for part 152 continues to read as follows:
Authority: 7 U.S.C. 136-136y.
2. In Sec. 152.25 by adding a new paragraph (g) to read as follows:
Sec. 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.
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(g) Minimum risk pesticides—

(1) Exempted products. Products containing the following active ingredients are exempt from the requirements of FIFRA, alone or in combination with other substances listed in this paragraph, provided that all of the criteria of this section are met.

Castor oil (U.S.P. or equivalent)
Cedar oil
Cinnamon and cinnamon oil
Citric acid
Citronella and Citronella oil
Cloves and clove oil
Corn gluten meal
Corn oil
Cottonseed oil
Dried Blood
Eugenol
Garlic and garlic oil
Geraniol
Geranium oil
Lauryl sulfate
Lemongrass oil
Linseed oil
Malic acid
Mint and mint oil
Peppermint and peppermint oil
2-Phenethyl propionate (2-phenylethyl propionate) Potassium sorbate
Putrescent whole egg solids
Rosemary and rosemary oil
Sesame (includes ground sesame plant) and sesame oil Sodium chloride (common salt)
Sodium lauryl sulfate
Soybean oil
Thyme and thyme oil
White pepper
Zinc metal strips (consisting solely of zinc metal and impurities)

(2) Permitted inerts. A pesticide product exempt under paragraph (g)(1) of this section may only include inert ingredients listed in the most current List 4A. This list is updated periodically and is published in the Federal Register. The most current list may be obtained by writing to Registration Support Branch (4A Inerts List) Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460.

(3) Other conditions of exemption. All of the following conditions must be met for products to be exempted under this section:

(i) Each product containing the substance must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient.

(ii) The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease transmitting bacteria or viruses, or claims to control insects or rodents carrying specific diseases, including, but not limited to ticks that carry Lyme disease.

(iii) The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10(a)(5)(i) through (viii).

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