UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 21, 1993

PESTICIDE REGULATION (PR) NOTICE 93-9

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticides

SUBJECT: Voluntary Reduced-Risk Pesticides Initiative

I. Purpose

The Environmental Protection Agency (EPA) wishes to encourage the registration of lower risk pesticide products containing new active ingredients in order to lessen the risks to human health and the environment. This PR Notice provides guidance on EPA's voluntary, interim process for identifying pesticides which may be eligible for priority treatment as lower-risk products. Applicants seeking registration of a new active ingredient are invited to provide a written rationale on why their pesticide may qualify for special consideration because it presents the opportunity for risk reduction. These rationales will be reviewed/evaluated and, if the pesticide demonstrates the opportunity for risk reduction, the EPA will use this as a factor in determining application review priority. This PR Notice also specifies the standard format for registrants to use when providing a justification for a reduced-risk pesticide to allow efficient processing within the Office of Pesticide Programs (OPP) in EPA.

II. Applicability

This Notice applies to all applicants seeking to register certain pesticide products containing a new active ingredient which may qualify for special consideration as a reduced-risk pesticide. These applicants are invited to provide an explanation accompanied by any supporting information on why their application and any associated tolerance petitions should receive special consideration based on such factors as reduced hazard, reduced opportunity for exposure, or both.

Recently, certain products containing new active ingredients which appeared to offer risk reduction opportunities have been given special consideration when EPA set priorities for registration actions. The new process described in this PR Notice is intended to broaden the approach and make it more systematic. EPA hopes to use the experience it gains from setting priorities for the review of new active ingredient applications to create an expanded and more sophisticated approach for future use. Thus, in the future, EPA will consider whether and how to extend similar treatment to applications and any associated tolerance petitions for new uses of currently registered active ingredients, when the applicant presents a documented claim that the proposed use qualifies as an opportunity for risk reduction. At present, however, in order to have a manageable workload, EPA will only consider such claims in establishing its review priorities for review of applications involving new active ingredients.

III. Effective Date

This PR Notice is effective immediately.

IV. Background

On July 20, 1992, EPA issued a Federal Register Notice (57 FR 32140) soliciting public comment on an announcement of future policy development intended to accomplish two goals: 1) to provide incentives to encourage the development, registration and use of pesticides or pest control practices that present lower risks to public health and the environment, and 2) to encourage the replacement of higher risk pesticides in the marketplace, especially the higher risk pesticides or specific uses for which no effective alternatives are available. The public was asked to provide the Agency with comments on specific issues identified in the notice and on any other topics believed to be germane to the subject.

Public Comment. In response, the Agency received comments from the pesticide industry; growers and agricultural associations; universities; other federal agencies; state and local governments; lawn care affiliates; and private citizens. EPA wishes to thank all individuals and organizations for their participation. The comments were numerous and insightful, and they will greatly assist the Agency in policy formulation. Copies of the comments are available for inspection at the Public Docket for the Office of Pesticide Programs under the document control number OPP-36184. The Docket is located in Room 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The Public Docket's hours of operation are 8:00 A.M. to 4:30 P.M., excluding holidays.

Workshop. Due to the potential impacts and complexity of this topic, EPA conducted a public workshop on October 5 and 6, 1992, entitled "Incentives for the Development, Registration and

Use of Reduced-Risk Pesticides," to explore the issues further. Over two hundred participants attended the workshop. The Agency appreciates the interest and enthusiasm of all attendees who provided candid, albeit differing viewpoints on how the Office of Pesticide Programs could accomplish its intended goals.

Reduced-Risk Strategy. Based on the input and recommendations received from both the written public comments and the workshop, EPA has developed both short- and long-term strategies to implement a comprehensive Reduced-Risk Policy.

Regarding the long-term strategy, the Administrator has identified four prime areas for action in order to fully implement a Reduced-Risk Pesticide Program:

1. Develop criteria for identifying lower risk pesticides and use them as a factor in scheduling reviews.

2. Streamline the overall registration process.

3. Make more information about pesticides available to users and others through the improvement of pesticide labels and the development of other information resources to permit more informed choices in the marketplace.

4. Consider rewarding developers of reduced-risk pesticides through possible statutory changes to extend the period of exclusive use of data under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), or to extend the period of patent protection.

EPA realizes that accomplishing these four objectives is necessary for the successful implementation of a formal policy; however, making positive strides in these areas will require both significant time and resources. In order to capture some of the potential benefits of such a program while the above longer term projects are in progress, the Agency is inviting registrants to participate in a short-term interim strategy. Under this voluntary approach, all applicants who believe they have developed a pesticide product containing a new active ingredient that may be characterized as presenting reduced risk to human health and the environment are invited to submit rationales to substantiate their claims.

V. Guidelines for Content of Reduced-Risk Rationales

While participation in the reduced-risk pesticides program is voluntary, those who elect to participate should fully address all of the following areas: (a) human health effects; (b) environmental fate and effects; (c) other hazards; (d) risk discussion; and (e) pest resistance and management. The Agency will consider all of these areas in setting priorities for review of these applications. However, these may not be the exclusive factors in all cases. If applicants identify additional criteria

that substantiate the argument that their product is indeed a reduced-risk pesticide, then EPA invites those applicants to submit rationales with any supporting data to verify such claims. The Agency will consider this additional information.

Applicants' documentation should contain both a discussion of the inherent reduced-risk properties of their product, as well as a comparison of those properties with the properties of the product's alternatives where appropriate. In considering the alternatives, the applicant should address all pesticide products registered for the same use(s) proposed in the application. Please note that the Agency does not expect the applicant to perform any additional testing to derive the data necessary to develop rationales for reduced risk. If any of the following information is not known, that fact should be noted in the rationale.

A. Human Health. Clearly identify the portion of the rationale which addresses the potential effects of the product on human health. In the format described in Part IV of this PR Notice, address each of the following aspects of the product and its use:

1. Acute Toxicity of the active ingredient and the formulations.

2. Reproductive, Developmental, Mutagenic and Neurotoxic Properties of the active ingredient.

3. Oncogenic and Other Chronic Effects of the active ingredient.

B. Environmental Fate and Effects. Clearly identify the portion of the rationale which addresses the potential ecological effects of the product and its environmental fate. Address each of the following aspects of the product and its use:

1. Mammalian Acute Toxicity

2. Avian Acute and Subacute Toxicity

3. Avian Reproductive Toxicity

4. Fish Acute and Chronic Toxicity

5. Aquatic Invertebrate Toxicity

6. Honeybee Acute Contact Toxicity

7. Effects on Terrestrial Plant Growth

8. Effects on Aquatic Plant Growth

in, or encouraging the adoption of, Integrated Pest Management (IPM) programs. This should include information on the effects of the pesticide on natural predators of the target pest, if such information is known.

VI. Formatting and Submittal Procedures

Formatting (A) and submittal (B) procedures for reduced-risk pesticide rationales are provided below. These procedures will enable EPA to easily identify the application for priority consideration. Also, applicants should note that it is unlawful to falsify any portion of an application. FIFRA Sections 12(a)(2)(M), 12(a)(2)(R) and 18 U.S.C. Section 1001 make such actions unlawful and can result in civil or criminal penalties.

A. Format. The reduced-risk rationale document must include the following elements in the order indicated: Title Page, Statement or Supplemental Statement of Data Confidentiality Claims, Cover Sheet to Confidential Attachment and Confidential Business Information (CBI) Reduced-Risk Attachment. Any supporting data must comply with PR Notice 86-5 requirements.

The Reduced-Risk Rationale must be bound as a separate entity and consecutively paginated beginning with the title page as page 1. The total number of pages must be represented on the title page. Do not include CBI on the title page. On the title page include title, author(s), date, and references (list any individual studies in the submittal package for which the rationale is providing commentary, summarizing, citing or referencing.

B. Submitting A Reduced-Risk Rationale Registration. Application The Reduced-risk rationale should accompany the registration application and supporting data packages. This PR Notice does not supersede established submittal procedures as addressed in PR Notice 91-5; rather, this PR Notice provides additional guidance for submitting the reduced-risk rationale. OPP uses distribution codes to facilitate the delivery of registration and other submissions within the program. When preparing your submission to mail or deliver to OPP, direct your submission to the Document Processing Desk and include the following distribution code: REDUCED-RISK APPL.

The submission delivered via the U.S. Postal Service should be directed to OPP using the following address:

Document Processing Desk (REDUCED-RISK APPL.)
Office of Pesticide Programs - H7504C
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

9. Potential Exposure to Non-target Organisms

10. Environmental Persistence (Soil and Water)

11. Mobility in Soil and Water

12. Transport in Air (Spray Drift and Volatility)

13. Bioaccumulation as Indicated by the Octanol/Water Partition Coefficient

C. Other Hazards. Clearly identify the portion of the rationale which addresses other potential human health and environmental hazards produced by the following:

1. Potential to Deplete Stratospheric Ozone thus increasing ultraviolet radiation.

2. Potential to Present a Hazard through Storage, Transportation, Mixing, Use, or Disposal based on its physical or chemical characteristics:

a. stability
b. flammability
c. corrosion characteristics
d. explodability
e. oxidizing or reducing action
f. storage stability

D. Risk Discussion. Clearly identify the portion of the rationale which addresses the following items:

1. Discuss the information which supports the claims that the new active ingredient presents reduced toxicity, reduced exposure to humans or non-target organisms, or reduced environmental burden.

2. Where alternative, registered pesticides or pest control practices exist, make a qualitative comparison between the risks posed by the new active ingredient under consideration and the other pesticides registered for that use, or the other current pest control practices.

E. Pest Resistance and Management. Clearly identify the portion of the rationale which addresses the following items:

1. Describe how the new product addresses the development of pest resistance, either to the new product itself or to existing pesticides registered for the same use.

2. Discuss the suitability of the new product for use

Submissions via personal or courier delivery should be directed to the Document Processing Desk between the hours of 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding federal holidays. OPP's Document Processing Desk is located at the following address:

Office of Pesticide Programs
Document Processing Desk (REDUCED-RISK APPL.)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

VII. For Further Information

For further information applicants may contact Stephanie R. Irene, Deputy Director, Registration Division at (703) 305-5447.

/signed/

Douglas D. Campt, Director
Office of Pesticide Programs