4/18/97

Pesticide Registration (PR) Notice 97-2

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

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: New Chemical, New Use, EUP, Non-Fast Track Amendments and Inert Ingredient Registration Priorities for Conventional Pesticides

This notice describes policies and procedures that will help in the prioritization and scheduling of applications for new chemical, new use, experimental use permits (EUP), non-Fast Track (NFT) Amendments (i.e., amendments that require science division reviews) and inert ingredient registration actions for conventional pesticides handled by the Registration Division (RD). Submissions to the Biopesticides and Pollution Prevention Division (BPPD) and to the new Antimicrobial Division (AD) are not covered by this notice. Submissions made to BPPD include microbial pesticides (bacteria, fungi, protozoans and viruses used to control pests), plant-pesticides (pesticidal substances introduced into plants along with the genetic material necessary for the production of the substances within the plants themselves) and biochemical pesticides (naturally occurring compounds that have a non-toxic mode of action) and certain other naturally occurring or essentially like naturally occurring compounds of low risk that have been approved by OPP for review in BPPD. Submissions made to AD include sanitizers, disinfectants, antifoulants, water filters, algicides, microbiocides, wood preservatives, phenols, inorganic halides and mineral acids. Methyl Bromide replacements are covered by this notice, unless they are subject to action by BPPD.

I. BACKGROUND

While pesticide registration productivity in OPP has increased in recent years, these gains have not been sufficient to offset the increased applications and requests made by registrants as well as the new requirements imposed by the Food Quality Protection Act (FQPA) of 1996. Since all the requests made on the Office of Pesticide Programs (OPP) cannot be met simultaneously, it is important that OPP address its customers' highest priorities in an efficient and equitable manner. For this reason all parties with applications pending in RD for the registration of new active ingredients, new uses, EUPs, NFT amendments and inert ingredients for conventional pesticides should submit in ranked order requests for their next top five priority actions by June 30, 1997. Submitter's ranked ordering should be consistent with the ordering specified in this PR Notice. OPP will combine these externally identified priorities with its own internal priorities (methyl bromide replacements, IR-4, etc.) and develop a schedule of when each action should be completed.

II. REGISTRATION DIVISION (RD) GOALS

RD has the following registration goals:

(1) Ensure that the nation's food supply continues to be safe, plentiful, and nutritious and strive to make it safer;

(2) Ensure that the nation's food production system continues to be safe and strive to make it safer;

(3) Reduce the potential risks that pesticides pose to human health (especially to infants and children) including:

  (a) reducing potential dietary risks (both food and drinking water) to consumers;

  (b) reducing potential risks to homeowners and others as a result of pesticide use in residential and other nonagricultural settings, and

  (c) reducing risks to workers who may be exposed to pesticides used in agriculture.

(4) Reduce the potential risks that pesticides pose to the earth's ozone layer, groundwater, aquatic organisms and wildlife;

(5) Increase the acreage subject to Integrated Pest Management (IPM) practices;

(6) Improve pest resistance management practices; and

(7) Reduce trade barriers, where consistent with U.S. health and environmental protection standards.

To meet these goals and the requirements of the Food Quality Protection Act, RD will prioritize its registration actions in the following order:

(a) methyl bromide alternatives

(b) reduced risk candidates

(c) USDA-EPA identified potentially vulnerable crops

(d) minor use priorities

(e) non-minor use priorities

(f) addressing trade irritants

Submitter's should explain how their priorities address RD's registration goals and are consistent with the above priorities.

III. METHYL BROMIDE ALTERNATIVES

If a registrant intends to submit a Methyl Bromide alternative, it does not have to be one of their five priorities. It becomes an EPA priority, and the Agency will attempt to meet the time frames specified in PR Notice 95-4 to the maximum extent possible. Expediting the availability of alternatives for the pesticide methyl bromide, which is scheduled to be phased-out under the Clean Air Act due to its ozone depleting potential, is one of EPA's highest priorities.

IV. REDUCED RISK CANDIDATES

If a registrant intends to submit or already has submitted a new chemical as a reduced risk candidate or a new use of a chemical already determined to be reduced risk by EPA, it must be one of their top five priorities. If the chemical is determined by OPP to be a reduced risk candidate, then RD will expedite the review and any resubmission that may be necessary can come in at any time, and the Agency will endeavor to review it at the earliest possible time. If the new active ingredient has been determined to be a reduced risk candidate by OPP, and if the submitter is simultaneously seeking registration in Canada, and if the application has been determined by Canada to be complete, the action can qualify for work-sharing between the two countries. While this work-sharing program is still in the "pilot" stage, it could result in reduced review times and greater harmonization.

V. USDA-EPA IDENTIFIED VULNERABLE CROPS

The United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) entered into a Memorandum of Understanding (MOU) on August 15, 1994. This MOU was amended on April 18, 1996. One of the purposes of this MOU was to establish a coordinated framework for collaborative efforts to develop pest management alternatives to a list of crop/pest combinations that are identified as potentially vulnerable (i.e. for which producers have only one or a limited number of efficacious alternatives or where pest resistance limits effective pest management or where regulatory action would result in pest management problems.)

The following crop/pest combinations have been identified by the USDA and EPA through interaction with State Agricultural Experiment Station research and extension faculty via the National Agricultural Pesticide Impact Assessment Program and state and regional Integrated Pest Management programs. In addition, commodity groups and producers were involved. The identified, potentially vulnerable crop/pest combinations are:

(1) alfalfa/aphids
(2) apples/mites
(3) apricots/mites
(4) artichokes/aphids
(5) blackberry, raspberry/pear psylla, rhizopus, rust
(6) cabbage/thrips, mites
(7) carrot/dodder, mites, fungal leaf diseases
(8) cole crops/aphids
(9) collards/alternaria, anthracnose, cercospora
(10) cranberry/mites
(11) cruciferous greens/alternaria, white rust
(12) grape/grape philoxera, black vine weevil
(13) leafy greens/aphids
(14) leek shallot/alternaria, botrytis, downy mildew
(15) lemon tangerine/pale color
(16) lettuce/aphids
(17) millet/annual grasses
(18) peaches/mites
(19) pecans/yellow pecan aphid
(20) peppermint, spearmint/weeds
(21) plums, prunes/mites, brown rot
(22) pumpkin/pigweed, nightshade
(23) radicchio/aphids
(24) rice/rice water weevil
(25) sorghum/cinch bug, broadleaf weeds
(26) spinach/fungal leaf diseases
(27) sugar cane/aphids, weeds
(28) sweet potato/weeds

If a registrant intends to submit an action that specifically addresses one or more of the crop/pest combinations listed above, it does not have to be one of their five priorities. It will become an Agency priority.

VI. MINOR USE PRIORITIES

A minor use priority is defined as any of the following:

(1) A single pesticide petition (for a new AI or new use) covering one or several major (and possibly minor) uses (as defined in section VII) and a single pesticide petition (for a new AI or new use) covering one or several minor uses. The two petitions may or may not be for the same pesticide.

(2) A single pesticide petition (for a new AI or new use) covering a major use and up to three pesticide petitions totaling up to three minor uses (as defined in section VII) where all petitions are for the same pesticide.

(3) Up to three pesticide petitions (for a new minor use AI or a new minor use) on up to three different pesticides totaling up to three minor uses (as defined in section VII).

The petitions may or may not be for the same pesticide.

(4) Experimental use permits (EUP) with or without a temporary tolerance on up to three minor uses (as defined in section VII) all for the same pesticide.

(5) A new non-food use chemical or a new use for a non-food use chemical that meets the definition for minor use (as defined in section VII).

(6) A full resubmission of a prior priority action where OPP required studies/data to be upgraded or repeated. A "full" submission requires that the registrant address all of the deficiencies identified in the Health Effects Division (HED) reviews or all of the deficiencies identified in the Environmental Fate and Ecological Effects (EFED) reviews. Partial resubmissions (i.e. residue chemistry deficiencies addressed but not toxicology issues) will not be scheduled. Full resubmissions are required since both HED and EFED are being reorganized with interdisciplinary branches to do these reviews.

(7) A non-fast track amendment (i.e. an amendment that requires science review) which

impacts at least one minor use (as defined in section VII).

(8) An inert ingredient which impacts at least one minor use (as defined in section VII).

VII. MINOR USE DEFINITION

For the purpose of addressing the Food Quality Protection Act in this PR notice, the legislation defines "minor use" to mean the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where--

(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

(2) the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and --

(A) there are insufficient efficacious alternative registered pesticides available for the use; or

(B) the alternatives to the pesticide use pose greater risks to the environment or human health; or

(C) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The Food Quality Protection Act defines "minor use" of a pesticide on an animal, a commercial agricultural crop or site, or for public health purposes in two different ways. The first definition identifies minor use crops as those with less than 300,000 total U.S. acres. The second definition requires an economic determination that a registrant does not have the market revenues or sufficient economic incentive to support pesticide registration for a use site.

MINOR USE CROPS

A pesticide use on a crop with less than 300,000 acres of total U.S. production is a minor use. This definition applies to numerous fruits, vegetables, spices, and horticulture and nursery crops. As an alternative to listing all minor use crops, a list of crops with more than 300,000 acres of U.S. production is provided below. Pesticide uses on commercial agricultural crops that do not appear on the list will automatically be considered minor uses. Because the first definition applies only to crop uses of less than 300,000 acres, non-crop uses or sites (such as animal uses, aquatic weed control, and rights-of-ways) are not evaluated under the first definition.

Agricultural Crops Grown on More Than 300,000 Acres

Almonds	Pecans
Apples	Popcorn
Barley	Potatoes
Beans, dry	Rice
Beans, snap	Rye
Canola	Sod Farms
Corn (sweet & field)	Sorghum
Cotton	Soybeans
Cottonseed	Sugarbeets
Grapes	Sugarcane
Hay (alfalfa & other)	Sunflower
Oats	Tobacco
Oranges	Tomatoes
Peanuts	Turf
	Wheat

MINOR USE ECONOMIC DEFINITION

A pesticide use on an agricultural crop grown on more than 300,000 acres or on a non-agricultural site may qualify as a minor use, provided the registrant can demonstrate that the use does not provide sufficient economic incentive to support registration. For purposes of this PR notice this economic determination can be made by using the equation:

(a) costs > gross revenues for 1 year for the specific site.

where:

Costs = incremental costs to register the site which are the costs of the additional data requirements to register the specific site. If registration costs are shared by more than one registrant, the costs should represent the registrant's share of the data requirement.

Revenues = registrant's gross sales which are the additional sales projected at full market potential for the specific site. EPA, in consultation with USDA, will make this determination based on the following information provided by the registrant:

Registrants that choose to submit priorities based on the economic definition for a minor use must provide the following:

1. A list of the registration data requirements and the estimated cost to generate the data for the specific site.

2. The Annual Domestic Sales or Revenues for the Specific Site: Provide the actual, annual value and quantity of domestic sales of the pesticide for the specific site. This value should be calculated as the average of the most recent 3 years. For the registration of a new site, annual revenues should be projected on the basis of full market potential.

3. A written summary addressing at least one of the criteria described in section VII (2)(A-D).

For a minor use priority that is determined to be a minor use as a result of the economic criteria specified above, the one year time frame for completion of reviews does not begin until after the economic determination has been completed.

IR-4 will be given an unlimited number of priorities for their minor use submissions. [For further information on minor uses, contact Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, EPA, 40l M St., S.W., Washington, D.C. 20460, (703) 308-8783, Fax (703) 308-6547, E-Mail - jamerson.hoyt@epamail.epa.gov. Also, registrants wishing to coordinate with USDA's IR-4 minor use program concerning minor crop registrations should contact: National Director; IR-4 Project Headquarters; New Jersey Agricultural Experiment Station; P.O. Box 231; New Brunswick, NJ 08903-0231; Phone (908) 932-9575; FAX (908) 932-8481; c-mail guest@aesop.rutgers.edu.

VIII. NON-MINOR USE PRIORITIES

A non-minor use priority can be defined as any of the following:

(1) A single pesticide petition (for a new AI or new use) covering one or several major use agricultural crops (as defined in section VII).

(2) An EUP with or without a temporary tolerance on a major use crop (as defined in section VII).

(3) A new non-food use chemical or a new use for a non-food use chemical that does not meet the criteria for minor use in section VII.

(4) A non-fast track amendment which impacts only major uses (as defined in section VII).

(5) An inert ingredient which impacts only major uses (as defined in section VII).

Non-minor use priorities as defined in this section must be prioritized by all submitters after their minor use priorities as defined in Section VI.

IX. TRADE IRRITANTS

OPP recognizes that national differences in tolerances/Maximum Residue Limits (MRLs) for pesticide residues in food may impede international trade in agricultural goods. Resolving these differences may be a high priority for growers trading partners, or others. Submitters pursuing international marketing strategies (especially in Canada and Mexico) for their pesticides, or who can reasonably anticipate that crops treated with their pesticides in other countries will be exported to the United States, are advised to consider the need to place a priority on seeking appropriate U.S. registrations and/or tolerances, to reduce the likelihood of adulterated food entering the U.S. and to avoid placing their customers at risk of regulatory action by U.S. authorities. To the extent that standards can be harmonized among countries engaged in agricultural trade, without lowering the level of protection standards, compliance and enforcement will be simplified and as a result, consumers, growers and the pesticide industry will benefit from greater consistency. If a tolerance or registration action that falls into this category is not one of the submitter's priorities, OPP reserves the right to substitute the new action for one of the submitter's identified priorities. OPP does not anticipate taking such an action except in exceptional cases.

Also, as explained in PR Notice 97-1, FQPA requires EPA to consider international standards in its tolerance setting decisions. Therefore, the Agency has requested information on international Maximum Residue Limits be included in tolerance petitions to facilitate reviews.

X. OPP PRIORITIES AND RESPONSIBILITIES

OPP reserves the right to insert its own priorities (i.e., new uses for repeat section 18s and other actions that OPP decides warrant priority attention) into the scheduling cycle.

OPP will schedule each priority action to the greatest extent feasible. OPP will complete each priority action or complete as much of the reviews and risk assessment as possible. Once OPP has completed its review, that priority action is considered completed. Any follow-up work that involves the need for further OPP scientific review of data will have to be reprioritized and rescheduled in a subsequent scheduling cycle.

XI. COMPLETE SUBMISSION

The data package to be reviewed for a given priority should be complete and submitted to OPP prior to the initiation of the scheduling cycle (June 30, 1997). This is necessary so that the scientists can estimate how long it will take to complete the work for each priority. Where data packages are not complete, the priority will not be scheduled until all the data are submitted regardless of the priority given by the submitter.

XII. SUBSTITUTIONS

Once priorities have been submitted, OPP strongly prefers that no changes or substitutions be made because even a single substitution can require a complex series of reassignments of science reviewers and changes in completion dates across multiple actions. However, if a party wishes to withdraw one of its priority actions and substitute another one for it, one such substitution will be permitted per party per scheduling cycle provided that (a) work on the existing priority has not already begun and (b) the new priority will be scheduled at the end of the priority list regardless of the priority of the action it is replacing.

XIII. Coordination with Tolerance Reassessment

The FQPA requires the Agency to reassess all tolerances and exemptions that predate the act to ensure that existing tolerances are consistent with the requirements of section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) as amended. For some pesticides scheduled for reassessment in the next two years, EPA may be unable to approve an application for a proposed new use or new tolerance until it completes the reassessment process for the pesticide. The reassessment process should not, however, delay evaluation and action on applications for "me-too" registrations issued pursuant to section 3(c)(7)(A) of FIFRA.

XIV. INFORMATION ON PRIORITIES TO BE SUBMITTED

For each priority the following information should be included:

1. Chemical name (ANSI Name and Trade Name)
2. Type of action (new chemical, new use, EUP, resubmission, etc.)
3. Site(s) (crops, non-crops)
4. Identification - REG#, CAS #, petition #, EUP #, file symbol (if known)
5. When data was submitted
6. What work needs to be done
7. Product manager assigned to chemical
8. All submissions must conform with the requirements of FQPA as specified in PR Notice 97-1.

XV. MAILING ADDRESS

Priorities should be submitted no later than June 30, 1997 to:

U.S. Postal Service

Peter Caulkins, Deputy Director
Registration Division (7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Personal/Courier Service Deliveries

Peter Caulkins, Deputy Director
Registration Division (7505C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Room 713, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

FAX

Peter Caulkins
(703) 305-6920

XI. FOR FURTHER INFORMATION

If you have questions regarding this notice, contact Peter Caulkins, Deputy Director, Registration Division at (703) 305-6550.

/signed/

Stephen L. Johnson, Director
Registration Division