

ENVIRONMENTAL PROTECTION AGENCY

[OPP-00574; FRL-6051-3]

Pesticides; Notice of the Registration Division's Fiscal Year 1999 Work Plan**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: EPA is publishing the fiscal year 1999 (FY99) work plan for the Office of Prevention, Pesticides, and Toxic Substances, Office of Pesticide Programs, Registration Division (RD) in keeping with efforts to improve the transparency and flexibility in the pesticide registration process.

With the publication of this FY99 work plan, RD is placing a large emphasis on new chemical, new use, and inert registration actions. In no way, however, will RD neglect the many other actions (e.g., label amendments, me-too actions, and emergency exemption requests) that are currently pending or will soon be submitted to the Agency. This FY99 work plan represents our current list and schedules for these important actions; however, the Agency has included room for flexibility in this FY99 work plan to ensure a quick response should an emerging public health or environmental issue arise. While forecasting such issues can be difficult, the Agency is committed to working with all affected parties to address their needs on an expeditious basis. Any submission which creates a modification to the schedule will, of course, require the appropriate justification and scientific data which will allow the Agency to make a sound, health-based decision.

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SUPPLEMENTARY INFORMATION: This **Federal Register** notice presents the FY99 work plan for the Registration Division (RD) in the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) at the Environmental Protection Agency (EPA). EPA is publishing RD's FY 99 work plan in order to improve the transparency and predictability of the pesticide registration process, while

maintaining sufficient flexibility to address emerging needs as appropriate.

I. General Information*A. Does This Notice Apply to Me?*

You may be particularly interested in this notice if you are a producer or registrant of a pesticide product. Your interest in this notice may depend upon your interest in the chemicals for which the Registration Division plans on making a decision (new conventional active ingredient and/or new tolerance petition) in fiscal year 1999.

B. How Can I Get Additional Information or Copies of This Document or Other Documents?

1. *Electronically.* You may obtain electronic copies of this document from the EPA internet Home Page at: <http://www.epa.gov/opprd001/workplan>.

2. *In person or by phone.* If you have any questions or need additional information about this action, you may contact the technical person identified in the "FOR FURTHER INFORMATION CONTACT" section.

II. Background

Historically, the Agency has reviewed new registration applications and tolerance petitions based upon a system of "first received, first reviewed." In 1993, the Agency switched its process for setting the review queue to a points based system. Under this points based system RD assigned priority points of differing values depending on the type of action (e.g. Section 18s = 75 points, Experimental Use Permits = 15 points, New Active Ingredients = 10 points). Priority points were also accrued for "aging," i.e., the longer a submission remained in the Agency before being completed, the more priority points it accrued. Actions with the highest number of priority points were generally the first to be completed by each of the science review divisions. Shortcomings of the point-based priority system have included: difficulty in planning and predicting priorities; some registrant priorities have not been completed in order; little perceived incentive for the registrants to submit comprehensive submissions; and poor reflection of Agency resources allocated toward registration progress.

Despite an increase in registration productivity, backlogs for some critical registration actions remained. To address this concern and to create a more efficient, predictable and equitable review queue, in June of 1995 the Agency launched a pilot priority system limiting the registrants to five (5)

priorities of their choice. Using this method, RD received approximately 170 priorities (designated #1-5) which were blended with Agency identified priorities (mainly IR-4 and repeat Section 18s) and placed into review. It was generally understood that priority #1 would be reviewed before priority #2 and priority #2 before #3, etc. PR Notice 95-6 (October 1995) officially announced the new priority policy and procedures, and requested that registrants submit their second round of five priorities (designated #6-10). This round of priorities included new active ingredients, new uses, and experimental use permits. The second round yielded 332 registrant priorities which were blended with EPA priorities.

In April 1997, EPA issued PR Notice 97-2 requesting a third round of 5 priorities (designated #11-15). The action eligibility for this round was expanded to include inerts and non-fast track amendments, including additional incentives to encourage more products for minor uses, methyl bromide substitutes, and alternatives to certain organophosphates. Registrants identified approximately 600 actions for prioritization in response to PR Notice 97-2. Changes required in the registration process by the Food Quality Protection Act have caused delays in completing the reviews for priorities 1 - 10; and delays in the scheduling of priorities 11 - 15.

Review of the registration process reveals a diversity of priority needs: there are statutory priorities such as minor use, me-too, and reduced risk actions; registrants frequently submit their top business priorities; USDA submits priorities on the basis of crop/pest combinations; priorities for grower groups are channeled directly to EPA or revealed by trends in Section 18 requests; and priorities for public interest groups are frequently related to contemporary issues, such as identifying methyl bromide replacement chemicals and alternatives to certain organophosphate pesticides. (Refer to Section C for definitions)

By publishing this FY99 RD work plan, the Agency expects to extend the transparency and predictability of the registration process. Based upon resource allocations for FY99, RD expects to make decisions on approximately 13 new conventional active ingredients, 75 (non Section 18) tolerance decisions and 23 food use inert ingredient decisions.

III. Overview

A. What are the Agency's Goals for This Work Plan?

By publishing this FY99 RD work plan, the Agency expects to extend the transparency and predictability of the registration process, while maintaining sufficient flexibility to address emerging needs as appropriate. Based upon resource allocations for FY99, RD expects to make decisions on approximately 13 new conventional active ingredients, 75 (non Section 18) tolerance decisions and 23 food use inert ingredient decisions.

With the implementation of the Government Performance and Result Act of 1993 (GPRA) OPP is tasked with doubling the annual number of registrations for reduced-risk new chemicals and bio-pesticides by the year 2005. To date RD has been averaging 2.5 new conventional reduced-risk chemicals per year. All registration activities including registration of new conventional chemicals, new uses, me-toos, antimicrobials, etc. (Refer to Section C for definitions) will meet the applicable standards mandated by law.

For fiscal year 1999, the Agency had originally anticipated being able to issue registration decisions for 15 conventional pesticides. However, in light of recent reductions in RD's operating plan, the Agency has reassessed this goal to 13 registration decisions for conventional pesticides. Resource reductions in FY99 have further reduced expected outputs for FY2000.

B. What Information Does the Work Plan Include?

The Registration Division's FY99 work plan includes the following information: (a) the quarter in which RD believes it can make a *decision* (please note that a decision does not necessarily mean a registration); (b) the chemical for which a registration action is requested; (c) the Trade Name associated with the chemical's end-use product for which the registration action is requested; (d) uses associated with the requested registration action; (e) name of the Registrant who has submitted the request; and (f) any relevant comments associated with the requested action. The above information is for both new conventional chemicals and conventional chemical new uses for which RD has committed to making a decision in FY99. In addition to the new conventional chemicals and conventional chemical new uses lists, RD has included a list of food use inerts and safeners, which require Health Effects Division review during FY99.

Additional food-use inert decisions (e.g., polymers) will also likely be made during FY99. Furthermore, EPA expects to issue 60 non-food use inert clearance decisions during FY99.

Once again, please note that RD is committing to decision dates and is not committing to registration dates. RD, in conjunction with the Health Effects Division and the Environmental Fate and Effects Division, has considered the amount of data associated with each requested actions in order to project a commitment date for decision making. These commitment dates could change or be delayed because of the following reasons: (a) data gaps; (b) significant risk issues; and (c) protracted negotiations on risk mitigation. With the publication of these commitment dates, RD is emphasizing new conventional chemicals, conventional chemical new uses, inerts and safeners but will not neglect the other actions (e.g., label amendments and me-too actions) pending or recently submitted to the Agency. Moreover, emerging needs will continue to be addressed as needed.

RD is posting the FY99 work plan on the EPA Internet web site [<http://www.epa.gov/opprd001/workplan>]. This web site will be updated periodically to provide current information on dates and other pertinent information for completed registration decisions and/or modified registration actions.

C. What are the Definitions of Certain Terms that are Used in the Work Plan?

1. *Active Ingredient*: means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a).

2. *Conventional Pesticide*: refers to any substance or mixture of substances intended for: a. Preventing, destroying, repelling, or mitigating any pest; b. Use as a plant regulator, defoliant, or desiccant, and c. Use as nitrogen stabilizer. This shall not include any antimicrobial, biological or plant pesticides.

3. *Experimental Use Permits*: means a permit pursuant to section 5 of FIFRA, including permits requiring the establishment of a temporary tolerance. The permit may be for a new active ingredient or for a new use of an active ingredient contained in a registered product

4. *Inert*: means a non-pesticidal active component of a pesticide product such as a surfactant or emulsifier.

5. *IR-4*: refers to the Inter-Regional Research Project Number 4 funded by

USDA and generates data to support minor use registrations, and coordinates the development of information on the clearance of these pesticides.

6. *Me-too*: refers to an application for registration of a pesticide product that is substantially similar or identical in its uses and formulation to products that are currently registered.

7. *Minor Uses*: refers to the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where;

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

(B) the Administrator, in consultation with the Secretary of Agriculture, determines that based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the registration or for such use and:

(i) there are insufficient efficacious alternative registered pesticides available for the use; and

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

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

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

8. *New Registration Application*: means any new application requiring Agency approval to register or amend a registration of a new or old chemical and its associated products.

9. *New Use*: when used with respect to a product containing a particular active ingredient, means:

a. Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of, a tolerance or food additive regulation under section 408 of the Federal Food, Drug and Cosmetic Act;

b. Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or

c. Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

10. *Non-fast Track Amendments*: involve label amendments where an active ingredient is registered for the use(s), but the product formulation is sufficiently different from existing products that product specific data are required to be submitted and reviewed. Data to be reviewed may include acute toxicity, product chemistry, and efficacy data.

11. Organophosphate (OP)

Alternative: a non-organophosphate conventional registration application request for either a new active ingredient or new use for which the crop/pest combination provides a reduced-risk (to human health and/or the environment) alternative to a registered organophosphate.

12. Polymer: a macromolecule formed by the chemical union of five or more identical combining units called monomers.

13. Reduced Risk: a conventional reduced risk pesticide use is defined as one which: (1) reduces pesticide risks to human health; (2) reduces pesticide risks to non-target organisms; (3)

reduces the potential for contamination of valued environmental resources; or (4) broadens adoption of integrated pest management strategies, or makes them more available or effective.

14. Safener: refers to an inert ingredient used to protect desired crop from the effects of the active ingredient, typically a herbicide.

15. Section 18s: means any action submitted under Section 18 of FIFRA which authorizes EPA to allow States to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist.

16. Tolerance Petition: refers to a formal request to establish a new tolerance or modify (raise, lower or

revoke) existing maximum residue levels.

IV. Registration Division's Fiscal Year 1999 Work Plan**A. New Chemical Registration Candidates**

The Registration Division's FY 1999 Work Plan identifies 20 new chemical candidates for decision-making during the fiscal year. Eight (8) of these chemicals are for reduced-risk chemicals, include 4 potential alternatives for organophosphate insecticides. These 20 candidates cover approximately 31 crops. From these 20 candidates, the Agency anticipates making 13 registration decisions.

Quarter	Chemical	Trade Name	Pesticide Type	Uses	Registrant	Comments
1 st Quarter	Tralkoxydim	Achieve	Herbicide	Wheat, Barley	Zeneca	Registered December 1998
2 nd Quarter	Emamectin Benzoate	Proclaim	Insecticide	Cole Crops	Novartis	
2 nd Quarter	CGA-248757	Action	Herbicide	Soybeans	Novartis	Reduced-Risk Chemical
2 nd Quarter	s-Dimethenamid	BAS 656034	Herbicide	All rac's currently registered with dimethenamid	BASF	
2 nd Quarter	Sulfosulfuron	MON 37500	Herbicide	Wheat	Monsanto	Registered January 1999 Reduced-Risk Chemical Joint Review with Canada
2 nd Quarter	Diflufenzopyr	Distinct	Herbicide	Corn	BASF	
2 nd Quarter	Lithium P. Sulfonate	Sulfotone	Insecticide	Wasp Bait Station	SC Johnson	Reduced-Risk Chemical OP Alternative
2 nd Quarter	n-Methylneodecanamide	Expel	Repellent	Indoor Use	Colgate-Palmolive	
2 nd Quarter	Bifenazate	Floramite	Insecticide	Ornamentals	Uniroyal	Reduced-Risk Chemical OP Alternative
2 nd Quarter	Chlorfenapyr	Pirate	Insecticide	Cotton	American Cyanamid	
3 rd Quarter	Propidine	Milestone	Repellent	Insect Repellent	Bayer	Reduced-Risk Chemical Joint Review with Canada
3 rd Quarter	Azafenidin		Herbicide	Citrus, Grape, Sugarcane, Vegetation Management	DuPont	
3 rd Quarter	Fenhexamid	Elevate	Fungicide	Grapes, Strawberries, Ornamentals	Tomen Agro	Reduced-Risk Chemical OP Alternative
3 rd Quarter	Fenpyroximate	Rally/Fulfill	Insecticide	Import Tolerances for Hops, Wine Grapes	Nihon Nohyaku	
3 rd Quarter	Pymetrozine		Insecticide	Cucurbits, Fruiting Veggies, Hops, Tobacco, Cotton	Novartis	Reduced-Risk Chemical OP Alternative
4 th Quarter	Trifloxystrobin	Flint	Fungicide	Pome Fruit, Grapes, Cucurbits, Peanuts, Turf, Bananas	Novartis	
4 th Quarter	Methoxyfenozide	Intrepid	Insecticide	Cotton, Pome Fruit	Rohm & Haas	Reduced-Risk Chemical OP Alternative
4 th Quarter	DPX-MP062	Muster	Insecticide	Cotton, Tomato, Pepper, Cole Crops,	DuPont	
4 th Quarter	Ethametsulfuron		Herbicide	Canola	DuPont	Reduced-Risk Chemical OP Alternative

Quarter	Chemical	Trade Name	Pesticide Type	Uses	Registrant	Comments
4 th Quarter	Gentamicin	Agrigent	Fungicide	Pome Fruit	Quimica	Withdrawn December 1998

B. New Use Candidates for Already-Registered Chemicals

The listing below identifies approximately 120 potential new uses for 37 already-registered chemicals. Many of these new uses are for

compounds currently classified as "reduced-risk pesticides." As opportunities arise during the course of the fiscal year, additional new use candidates may be added to this list for decision-making. Any additions to this

list will be subjected to the prioritization criteria outlined in Pesticide Registration Notice 97-2. From these new use candidates, the Agency anticipates issuing 100 new use decisions.

Quarter	Chemical	Trade Name	Pesticide Type	Uses	Registrant	Comments
1 st Quarter	Dicamba	Banvel	Herbicide	Soybeans, Wheat, Cotton, Barley, Asparagus	BASF	Tolerance Published 01/06/99
1 st Quarter	Picloram	Tordon	Herbicide	Sorghum	Dow Agrosciences	Tolerance Published 01/05/99
1 st Quarter	Avermectin		Insecticide	Chili Peppers, Grapes	Novartis	
1 st Quarter	Hexythiazox	Savy	Insecticide	Hops	Gowan	Tolerance Published 10/16/98
1 st Quarter	Cymoxanil	Curzate	Fungicide	Grapes, Tomatoes	DuPont	Tolerance Published 02/10/99
1 st Quarter	Tebuconazole	Elite, Folicur	Fungicide	Grapes, Grasses Grown for Seed	Bayer	Tolerance Published 01/08/99
1 st Quarter	Tribasic Copper Sulfate, Copper Oxychloride, Copper Hydroxide, Copper salts of fatty and rosin, Cuprous Chloride, Cuprous Oxide		Fungicide	Several Uses	Premium Compounding, Griffin, Monterey Chem. Co.	
1 st Quarter	Copper Ethylenediamine	Inferno	Fungicide	Potato	IR-4	Tolerance Published 01/04/99
2 nd Quarter	Azoxystrobin	Heritage, Quadris	Fungicide	Canola, Peanut Hay, Pistachios, Tree Fruits, Wheat, Turf, Potatoes, Stone Fruit, Cucurbits	Zeneca	Reduced-Risk Chemical
2 nd Quarter	Triallate	Fargo	Herbicide	Sugar Beets	Monsanto	
2 nd Quarter	Halosulfuron	Permit	Herbicide	Sugarcane, Popcorn, Sweet and Field Corn, Cotton, Rice, Grain Sorghum, Tree Nuts	Monsanto	
2 nd Quarter	Quinclorac	Facet	Herbicide	Sorghum, Wheat	BASF	Sorghum is on the USDA Vulnerable Crops List

Quarter	Chemical	Trade Name	Pesticide Type	Uses	Registrant	Comments
2 nd Quarter	Tebufoenozide	Confirm	Insecticide	Pome Fruit, Cotton, Leafy Vegetables, Cole Crops, Sugarcane, Fruiting Vegetables, Pecans, Forestry, Ornamentals, Cranberry, Turnips, Caneberry, Canola, Mint, Blueberry	Rohm & Haas	Reduced-Risk Chemical
2 nd Quarter	Pyriproxyfen	Knack	Insecticide	Tree Crops, Apples, Pears, Walnuts	Valent	Reduced-Risk Chemical
2 nd Quarter	Fludioxanil	Switch, Medalion	Fungicide	Grapes, Turf	Novartis	Reduced-Risk Chemical
2 nd Quarter	Iprodione	Rovral	Fungicide	Cottonseed	Rhone-Poulenc	
2 nd Quarter	Arsanilic Acid (EUP)		Fungicide	Grapefruit	Fleming Laboratories	
2 nd Quarter	Clofentezine	Apollo	Insecticide	Apples	AgrEvo	
3 rd Quarter	Cyfluthrin		Insecticide	Potato	Bayer	
3 rd Quarter	Fosetyl-al	Aliette	Fungicide	Bananas, Grapes, Macademia Nuts	Rhone-Poulenc	Reduced-Risk Chemical
3 rd Quarter	Spinosad	Spintor	Insecticide	Tuberous and Corm Vegetables	Dow Agrosiences	
3 rd Quarter	Pyriproxyfen	Knack	Insecticide	Citrus, Fruiting Vegetables	Valent	
3 rd Quarter	Imidacloprid	Admire	Insecticide	Tuberous and Corm Vegetables Subgroup, Cucurbit, Watercress	Bayer, IR-4	
3 rd Quarter	Cyromazine		Insecticide	Bulb Vegetables, Mango, Cotton, Potato, Radish, Sweet Corn	Novartis	Sorghum is on the USDA Vulnerable Crops List
3 rd Quarter	Glufosinate Ammonium	Liberty	Herbicide	Canola, Potato, Sugar beet	AgrEvo	
4 th Quarter	Difconazole	Dividend	Fungicide	Bananas	Novartis	
4 th Quarter	Fenpropathrin	Danitol	Insecticide	Melons, Citrus, Brassica	Valent	
4 th Quarter	Dazomet	Atlante	Fumigant	Strawberries, Tomatoes	BASF	Reduced-Risk Chemical
4 th Quarter	Propazine	Milo Pro	Herbicide	Sorghum	Griffin	
4 th Quarter	Myclobutanil	Rally/Nova	Fungicide	Asparagus, Snap Beans, Caneberry, Gooseberry, Currant, Mint, Strawberry	Rohm-Haas, IR-4	
4 th Quarter	Kresoxim-methyl	Sovran	Fungicide	Grapes, Pecan, Pome Fruit	BASF	
4 th Quarter	Spinosad		Insecticide	Cucurbits, Stone Fruit, Legume, Corn, Sorghum, Wheat	Dow Agrosiences	Reduced-Risk Chemical
4 th Quarter	Glyphosate	Roundup	Herbicide	Barley, Canola, Sugar Beet	Monsanto	Reduced-Risk Chemical
4 th Quarter	Bifenthrin	Capture	Insecticide	Cucurbits, Eggplant, Legumes, Lima Beans, Head and Stem Brassica Subgroup, Artichoke, Canola	IR-4	
4 th Quarter	Chlorothalonil	Bravo	Fungicide	Non-bell Peppers, Almonds, Asparagus, Mango, Pistachio	IR-4 and GB Bioscience	

C. Inert¹ and Safener² Registration Decisions

Quarter	Chemical	Uses
1 st Quarter	Rhodamine B	Inert
2 nd Quarter	HOE 107892	Safener
2 nd Quarter	MON 4660	Safener
3 rd Quarter	MON 13900	Safener
3 rd Quarter	Dichlormid	Safener

Quarter	Chemical	Uses
4 th Quarter	DMSO	Inert
4 th Quarter	Isophorone	Inert

¹Inert = non-pesticidal active component of a pesticide product such as a surfactant or emulsifier.

²Safener = inert ingredient used to protect desired crop from the effects of the active ingredient, typically a herbicide.

List of Subjects

Environmental protection, Pesticides, Tolerances.

Dated: March 2, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

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