

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300731; FRL 6034-9]

RIN 2070-AB78

Bifenthrin; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends a time-limited tolerance for residues of the insecticide bifenthrin and its metabolites in or on canola at 0.5 part per million (ppm) for an additional 18-month period, to March 30, 2000. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on canola. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement of a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation becomes effective October 7, 1998. Objections and requests for hearings must be received by EPA, on or before December 7, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP-300731, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, OPP-300731, must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk

may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Follow the instructions in Unit II. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 267, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-308-9356; e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of September 5, 1997 (62 FR 46894) (FRL-5740-6), which announced that on its own initiative and under section 408(e) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), it established a time-limited tolerance for the residues of bifenthrin and its metabolites in or on canola at 0.5 ppm, with an expiration date of September 30, 1998. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement of a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

EPA received requests to extend the use of bifenthrin on canola for this year's growing season due to the situation which has remain unchanged. Aphid populations in canola have significantly increased in recent years, and are not adequately controlled through available means. Mild and wet winters have exacerbated this situation, as they allow high aphid carryover from the previous year, and delay planting so that flowering of the canola occurs when aphid populations are at their peak. Significant economic losses were expected without adequate control of aphids in canola. After having reviewed the submission, EPA concurs that emergency conditions exist for Idaho, Oregon, and Washington states. EPA has authorized under FIFRA section 18 the use of bifenthrin on canola for control of aphids in canola.

EPA assessed the potential risks presented by residues of bifenthrin in or on canola. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA

section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of September 5, 1997 (62 FR 46894). Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerance is extended for an additional 18 month period. Although this tolerance will expire and is revoked on March 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on canola after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

I. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by December 7, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a

summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

II. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300731] (including any comments and data submitted electronically). 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The

official rulemaking record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

III. Regulatory Assessment Requirements

A. Certain Act and Executive Orders

This final rule extends a time-limited tolerance that was previously extended by EPA under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). In addition, this final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

Since this extension of an existing time-limited tolerance does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon

a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of

section 3(b) of Executive Order 13084 do not apply to this rule.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 28, 1998.

Arnold E. Layne,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

§ 180.442 [Amended]

2. In §180.442, by amending the entry for "Canola, seed" in the table in paragraph (b) by changing the date "9/30/98" to read "3/30/00."

[FR Doc. 98-26901 Filed 10-6-98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300738; FRL-6036-8]

RIN 2070-AB78

Fludioxonil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil (4-

(2,2-difluoro 1,3 benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile) in or on the following raw agricultural commodities (RACs): rape seed, rape forage, peanuts, meat (hulls removed), peanut hay, sunflower seed, leafy vegetables except brassica, brassica leafy vegetables, legume vegetables, foliage of legume vegetables, fruiting vegetables except cucurbits, cucurbit vegetables, forage, fodder, and straw of cereal grains, grass, forage, fodder, and hay, and non-grass animal feeds at 0.01 parts per million (ppm); root and tuber vegetables, leaves of root and tuber vegetables, bulb vegetables, cereal grains, and herbs and spices at 0.02 ppm; and cotton seed and cotton gin byproducts at 0.05 ppm. Novartis Crop Protection, Inc. requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

DATES: This regulation is effective October 7, 1998. Objections and requests for hearings must be received by EPA on or before December 7, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300738], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300738], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e mail) to: opp.docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by

the docket control number [OPP-300738]. No Confidential Business Information (CBI) should be submitted through e mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Registration Division [7505C], Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-308-9354, e mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 26, 1998 63 FR 45497 (FRL-6023-4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a announcing the filing of a pesticide petition (PP 8F4978) for tolerances by Novartis Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419. This notice included a summary of the petition prepared by Novartis Crop Protection Inc., the registrant. There were no comments received in response to the Notice of Filing.

The petition requested that 40 CFR 180.516 be amended by establishing tolerances for residues of fludioxonil in or on the following RACs: rape seed and rape forage (reported as canola in the Notice of Filing), peanuts, meat (hulls removed) and peanut hay (reported as peanuts in the Notice of Filing), sunflower seed, leafy vegetables except brassica (Crop Group 4); brassica leafy vegetables (Crop Group 5); legume vegetables (Crop Group 6); foliage of legume vegetables (Crop Group 7); fruiting vegetables except cucurbits (Crop Group 8); cucurbit vegetables (Crop Group 9); forage, fodder, and straw of cereal grains (Crop Group 16); grass, forage, fodder, and hay (Crop Group 17); and non-grass animal feeds (Crop Group 18) at 0.01 ppm; root and tuber vegetables (Crop Group 1); leaves of root and tuber vegetables (Crop Group 2); bulb vegetables (Crop Group 3); cereal grains (Crop Group 15); and herbs and spices (Crop Group 19) at 0.02 ppm; cotton seed, and cotton gin byproducts at 0.05 ppm.

I. Risk Assessment and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to