List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, and Reporting and recordkeeping requirements.

Dated: February 5, 1997.

John P. DeVillars,

Regional Administrator, Region I.

Part 70, title 40 of the Code of Federal Regulations is amended as follows:

PART 70—[AMENDED]

1. The authority citation for Part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

2. Appendix A to Part 70 is amended by adding the entry for Maine in alphabetical order to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Maine

(a) Department of Environmental Protection: submitted on October 23, 1995; source category-limited interim approval effective on March 24, 1997; source category-limited interim approval expires March 22, 1999.

(b) [Reserved]

* * * * *

[FR Doc. 97–4327 Filed 2–20–97; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180

[OPP–300449; FRL–5583–4]

RIN 2070-AB78

Benoxacor; Time-Limited Tolerances for Residues

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2*H*-1,4-benzoxazine (benoxacor) when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor. This regulation is being issued in response to a petition for the establishment of a tolerance for residues of benoxacor requested by Ciba-Geigy Corp.

EFFECTIVE DATE: This regulation becomes effective February 14, 1997 and expires on February 14, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300449], 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-300449], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), 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. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

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 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-300449]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed on-line at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Kerry B. Leifer, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Crystal Drive Jefferson Davis Hwy., Arlington, VA, (703)-308-8811, e-mail: leifer.kerry @epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, at the request of Ciba, Crop Protection, pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), is establishing tolerances for residues of the inert ingredient (safener) 4-(dichloroacetyl)-3,4-dihydro-3-methyl-2*H*-1,4-benzoxazine (benoxacor) at 0.01 part per million (ppm) in or on raw agricultural commodities for which tolerances have been established for metolachlor. These tolerances will expire on February 14, 1998. A notice of filing of a tolerance petition, including the petitioner's summary of the information, data and arguments in support of their petition was published in the Federal Register on November 5, 1996 (61 FR 56954).

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

I. Background and Statutory Authority

A time-limited tolerance was established for benoxacor when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor and published in the Federal Register on June 30, 1992 (57 FR 29031). The time-limited tolerance expired on December 1, 1996. This time-limited tolerance was established to allow for the submission and Agency review of chronic toxicity/oncogenicity data on benoxacor. The requisite chronic toxicity/oncogenicity studies in the rat and mouse were submitted by the petitioner; however, the Agency's review of the data is not yet complete. In order to allow the for the continued use of benoxacor as a safener in formulations of metolachlor while the EPA continues its review of the submitted oncogenicity data, the petitioner has requested that the time-limited tolerance be extended until such time as the Agency is able to make a definitive determination as to the safety of the tolerance.

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures.

New section 408(b)(2)(A)(i) 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 mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure

through drinking water, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.'' Section 408(b)(2)(D) specifies factors EPA is to consider in establishing a tolerance. Section 408(b)(3) requires EPA to determine that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food and that the tolerance be set at a level at or above the limit of detection of the designated method. Section 408(b)(4) requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. If so, and EPA does not propose to adopt that level, EPA must publish for public comment a notice explaining the reasons for departing from the Codex level. Section 408 governs EPA's establishment of exemptions from the requirement for a tolerance using the same safety standard as section 408(B)(2)(A) and incorporating the provisions of section 408(b)(2)(C) and (D). Section 408(d) allows for the filing of a petition proposing the issuance of a regulation establishing, modifying, or revoking a tolerance or tolerance exemption for a pesticide chemical residue in or on a food.

II. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no observed effects level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered by EPA to pose a reasonable certainty of no harm.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure calculations based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. A time-limited tolerance was established for benoxacor when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor and published in the Federal Register on June 30, 1992. The time-limited tolerance expired on December 1, 1996.

EPA has reassessed the toxicology data base for benoxacor including new reproductive, chronic and carcinogenicity studies provided by the petitioner as part of this action to extend the time-limited tolerances for benoxacor. EPA has sufficient data to assess the hazards of benoxacor and to make a determination on aggregate exposure, consistent with section 408(b)(2), for the time-limited tolerances for residues of benoxacor at 0.01 ppm in or on raw agricultural commodities for which tolerances have been established for metolachlor. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic toxicity.* Based on the available chronic toxicity data, EPA has established the RfD for benoxacor at 0.004 milligrams (mg)/kilogram(kg)/day. This RfD is based on a 2–year feeding study in rats with a NOEL of 0.4 mg/kg/day and an uncertainty factor of 100. The uncertainty factor of 100 was applied to account for inter-species extrapolation (10) and intra-species variability (10). Increased non-neoplastic lesions of the stomach (including epithelial hyperplasia) and liver (including centrilobular enlargement and hepatocyte vacuolation in males) were the effects observed at the lowest effect level (LEL) of 2.0 mg/kg/day.

2. *Acute toxicity.* Based on the available acute toxicity data, EPA has

determined that benoxacor does not pose any acute dietary or nondietary risks.

3. *Carcinogenicity*. Based upon findings of a carcinogenic effect in the nonglandular stomach of rats and mice, benoxacor has been referred to the Office of Pesticide Program's Health Effects Division Cancer Peer Review Committee for classification as to its carcinogenicity. It is scheduled for review and classification in February 1997. The Agency has determined that, for the purposes of this time-limited tolerance and until such time as the Peer Review Committee makes a determination regarding the nature of the carcinogenic response and mode of action of benoxacor, a risk assessment of benoxacor utilizing the RfD derived from the chronic toxicity data is appropriate due to the nature of the tumor (forestomach) and the low incidence of tumors at the high dose level of 41 mg/kg/day.

B. Aggregate Exposure

For the purpose of assessing chronic dietary exposure from benoxacor, EPA considered the proposed benoxacor tolerance of 0.01 ppm and the raw agricultural commodities for which tolerances have been established for metolachlor. There are no other established U.S. tolerances for benoxacor, and there are no other registered uses for benoxacor on food or feed crops in the United States. In conducting this exposure assessment, EPA assumed tolerance level residues and 100 percent crop treated, resulting in a large overestimate of dietary exposure and protective of any chronic dietary exposure scenario.

Other potential sources of exposure of the general population to residues of pesticide chemicals are residues in drinking water and exposure from non-occupational sources. There is no established Maximum Concentration Level for residues of benoxacor in drinking water and no health advisory levels for benoxacor in drinking water have been established.

Review of the environmental fate data submitted by the petitioner indicates that benoxacor is mobile and hydrolyzes slowly at low pH's, but rapidly degrades in the soil (half-life of 49 days under aerobic conditions and 70 days anaerobically). Although the Agency does not have available data to perform a drinking water assessment at this time, exposure to residues of benoxacor in drinking water is not expected to result in unacceptable aggregate risk. This conclusion is based on the low application rate, the lack of significant acute oral toxicity, and the low percentage of the RfD occupied by dietary exposure, as well as an assessment of other pesticide chemicals which shows that except for highly mobile, persistent and acutely toxic chemicals, a significant contribution to aggregate risk to drinking water is unlikely.

EPA has evaluated the estimated non-occupational exposure to benoxacor. All metolachlor products to which benoxacor is added as a safener are commercial agricultural products not registered for residential use. The potential for non-occupational exposure to benoxacor by the general population is therefore unlikely except for the potential residues in food crops discussed above.

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide chemical's residues and ''other substances that have a common mechanism of toxicity.'' While the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide chemical shares a common mechanism of toxicity with any other substances, EPA does not at this time have the capability to fully resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticide chemicals. The Agency hopes that the results of this pilot process will enable the Agency to apply common mechanism issues to its pesticide risk assessments. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to risk assessments. Therefore, the Agency believes that in most cases there is no ''available information'' concerning common mechanism that can be applied to tolerance decisions. ''Available information'' as used in this context includes both the toxicity data, as well as policies and methodologies for conducting cumulative risk assessments. In most cases, although data may be available, policies and methodologies have not been developed to permit their use. When the Agency has determined that a particular pesticide chemical may share a significant common mechanism with other chemicals, a tolerance decision may be affected by common mechanism issues. Conversely, when the Agency has determined that a pesticide chemical does not share a common mechanism of toxicity with other chemicals, the tolerance decision will state this and provide supporting information. Where the Agency cannot determine whether a common mechanism of toxicity is operating because of lack of available information, a tolerance decision will be based upon the best available and useful information for the individual chemical, and a risk assessment will be performed for the individual chemical assuming that no common mechanism of toxicity exists.

In the case of benoxacor, EPA has not yet determined whether to include this chemical in a cumulative risk assessment. This tolerance decision therefore does not take into account common mechanism issues. The Agency will reexamine the tolerances for benoxacor during the tolerance reassessment process or when the time-limited tolerance approaches expiration.

C. Determination of Safety for U.S. Population

1. *Chronic risk*. Based on the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure to benoxacor will utilize 4.8 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD. Acceptable, reliable data are not available to quantitatively assess risk from drinking water. However, EPA concludes that there is a reasonable certainty that no harm to the U.S. population will result from aggregate exposure to benoxacor residues.

2. *Acute risk*. Due to the minimal acute toxicity of benoxacor, there are no concerns for acute dietary, occupational, and non-occupational exposures to benoxacor.

D. Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of benoxacor, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide chemical exposure during prenatal development to one or both parents. Reproductive toxicity studies provide information relating to effects from exposure to a pesticide chemical on the reproductive capability of mating animals and data on systemic toxicity.

Based on current toxicological data requirements, the data base for benoxacor relative to pre- and post-natal toxicity is complete. EPA notes developmental toxicity NOELs of 100 mg/kg/day in rats and 12.5 mg/kg/day in rabbits. Developmental toxicity was observed in rats at 400 mg/kg/day; these effects occurred in the presence of maternal toxicity. In rabbits, developmental alterations were noted at the maternally toxic dose of 62.5 mg/kg/day. The developmental NOELs are more than 250- and 31-fold higher in the rats and rabbits respectively, than the NOEL of 0.4 mg/kg/day from the chronic toxicity/oncogenicity study in rats, which is the basis of the RfD.

In the 2–generation reproductive toxicity study in rats, the reproductive toxicity NOEL of 4.57 mg/kg/day was greater than the parental (systemic) toxicity NOEL (3.55 mg/kg/day in males and 4.51 mg/kg/day in females. The NOEL of 4.57 mg/kg/day for reproductive (pup) toxicity was 11-fold higher than the NOEL of 0.4 mg/kg/day from the chronic toxicity/oncogenicity study in rats,, which is the basis of the RfD. The reproductive (pup) lowest observed effect levels (LOEL) of 64 mg/kg/day (first generation; F1) and 72.25 mg/kg/day (second generation; F2) are based on decreased body weights on lactation day 21. Because these reproductive effects occurred in the presence of parental (systemic) toxicity, these data do not suggest an increased post-natal sensitivity to children and infants (i.e., that infants and children might be more sensitive than adults) to benoxacor exposure.

FFDCA section 408 provides that EPA shall apply an additional uncertainty (safety) factor for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of exposure (safety) is appropriate. EPA believes that reliable data support using standard uncertainty factors (usually 100x for combined inter- and intraspecies variability) and not the additional uncertainty factor when EPA has a complete data base and when the severity of the potential effect in infants and children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the traditional uncertainty factors.

Based on current toxicological data requirements the data base for benoxacor relative to pre- and postnatal toxicity is complete. As mentioned above, because both developmental and reproductive effects occurred in the presense of parental (systemic) toxicity, these data do not suggest an increased pre- or postnatal sensitivity of children and infants to benoxacor exposure. Therefore, EPA concludes, upon the basis of reliable data that a 100-fold uncertainty factor is adequate to protect the safety of infants and children and an additional safety factor is not warranted.

1. *Chronic risk*. Based on the TMRC exposure estimates, EPA has concluded that the percentage of the RfD that will be utilized by dietary exposure to residues of benoxacor ranges from 3.3 percent for pregnant females 13+ years old, up to 20 percent for non-nursing infants.

FFDCA section 408 provides that EPA shall apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety is appropriate. Based on current toxicological data requirements, the data base for benoxacor relative to pre- and post-natal toxicity is complete. As mentioned above, because reproductive effects occurred in the presence of parental (systemic) toxicity, these data do not suggest an increased post-natal sensitivity of children and infants to benoxacor exposure, and therefore an additional safety factor was not applied. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to benoxacor residues.

2. *Acute risk*. Due to the minimal acute toxicity of benoxacor, EPA concludes that there is a reasonable certainty of no harm for infants and children resulting from acute dietary or non-occupational exposures to benoxacor.

IV. Other Considerations

The nature of the residue in plants and animals is adequately understood for this tolerance. There are no Codex maximum residue levels established for residues of benoxacor on commodities for which a tolerance for metolachlor exist. Adequate enforcement methodology, GC/NPD, is available to enforce the tolerance expression. An analytical methodology for the determination of benoxacor and its metabolites in plant and animal commodities (Ciba Analytical Method AG536(C)) is available from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA.

V. Conclusion

Therefore, time-limited tolerances are established for residues of benoxacor when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor. These tolerances will expire on February 14, 1998.

VI. 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 the new section 408(d) 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 its current procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by April 22, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) 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 requester's contentions on such issues, and a summary of any evidence relied upon by the requester (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 requester would, if established, resolve one or more of such issues in favor of the requester, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requester 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.

VII. Public Docket

A record has been established for this rulemaking under docket number [OPP-300449]. A public version of this record, 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 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. EPA has also established a special record for post-FQPA tolerances which contains documents of general applicability. This record can be found in the same location.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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 The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines ''a significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

This action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent enactment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence the RFA is inapplicable.

Under 5 U.S.C. 801(a)(1)(A), EPA submitted 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 General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(a).

List of Subjects in 40 CFR Part 180

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

Dated: February 14, 1997.

Peter Caulkins,

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.

2. By revising § 180.460 to read as follows:

§ 180.460 Benoxacor; tolerances for residues.

Tolerances are established for residues of the inert ingredient (safener) benoxacor (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2*H*-1,4-benzoxazine) when used in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor. These tolerances expire on February 14, 1998.

[FR Doc. 97–4495 Filed 2–20–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 410 and 415

[BPD–852–CN]

RIN 0938–AH40

Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1997; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Correction of final rule with comment period.

SUMMARY: This document corrects technical errors that appeared in the final rule with comment period published in the Federal Register on November 22, 1996 entitled ''Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1997.''

EFFECTIVE DATE: January 1, 1997.

FOR FURTHER INFORMATION CONTACT: Stanley Weintraub, (410) 786–4498.

SUPPLEMENTARY INFORMATION:

Background

In the Federal Register Document dated November 22, 1996, there were a number of technical errors. In Addendum B, beginning on page 59595, we inadvertently printed incorrect information for certain codes. The corrections appear in this document under the heading ''Correction of Errors.''