(c) *Tolerances with regional registrations.** * *

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–15981 Filed 6–17–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300486B; FRL–5724–9]

RIN 2070–AB78

Bromoxynil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes the following time-limited tolerances, to expire on January 1, 1998, for the residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) and its metabolite DBHA (3,5-dibromo-4-hydroxybenzoic acid) resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton: undelinted cottonseed at 7 parts per million (ppm), cotton gin byproducts at 50 ppm, and cotton hulls at 21 ppm. (Active ingredient codes are 35302 for the octanoic acid ester, and 128920 for the heptanoic acid ester. CAS Reg. Nos. are 1689–99–2 for the octanoic acid ester, and 56634–95–8 for the heptanoic acid ester.) In addition, this document revises tolerances for the residues of bromoxynil, resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton, in or on cattle, hogs, horses, goats, and sheep to 0.5 ppm in meat, 3.0 ppm in meat by-products, and 1.0 ppm in fat. Further, this document establishes tolerances for residues of bromoxynil, resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton, at 0.1 ppm in milk; at 0.05 ppm in eggs; and at 0.05 ppm in poultry meat, meat by-products, and fat. The tolerances for the cotton commodities will expire and are revoked on January 1, 1998. After January 1, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations. Rhone-Poulenc AG Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting a tolerance on cottonseed.

EFFECTIVE DATE: This rule becomes effective June 18, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300486B], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Information and Records Integrity Branch, Information Resources and Services 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. 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 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 in 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–300486B]. 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.

Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Product Manager (PM) 25, 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. 241, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6027, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 24, 1995 (60 FR 27414), EPA established a time-limited tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, for residues of the herbicide bromoxynil, (3,5-dibromo-4-hydroxybenzonitrile) on cottonseed. This tolerance expired on April 1, 1997. The tolerance was established in response to a petition filed by the Rhone-Poulenc AG Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709.

In the **Federal Register** of December 24, 1996 (61 FR 67807) (FRL–5576–8), EPA issued a notice of filing that stated that the Rhone-Poulenc AG Company had submitted a pesticide petition to EPA proposing to extend the time-limited tolerance on cottonseed. Comments in response to the notice of filing were received from the Union of Concerned Scientists, the Pesticide Action Network, the Edmonds Institute, Friends of the Earth, the Environmental Defense Fund, and many individuals.

In the **Federal Register** of May 2, 1997 (62 FR 24065) (FRL–5617–5), EPA issued a proposed rule for establishment of tolerances on cotton commodities and poultry, and revision of tolerances on animal commodities. The Agency issued this proposed rule because, after review of the petition, the Agency determined that as a result of bromoxynil use on cotton: (1) A higher tolerance will be needed for cottonseed; (2) existing tolerances for bromoxynil on animal commodities (meat, meat byproducts, and fat) need to be raised; and (3) additional tolerances will be needed for other cotton commodities (undelinted cottonseed and cotton gin byproducts) and other animal commodities (poultry meat, meat by-products, fat; eggs; and milk).

Written comments on the proposed rule were to be received within 17 days of issuance of the **Federal Register** notice. Under section 408 of the FFDCA, the Agency is required to provide a 60–day comment period on proposed rules unless EPA finds for good cause that it would be in the public interest to provide a shorter period. The Agency shortened the comment period on the bromoxynil tolerances to 17 days because notice had been provided on the intention of establishing a tolerance permitting use of bromoxynil on cotton, and cotton growers faced a potential hardship if a decision was not made expeditiously.

Following publication of the May 2 proposed rule, several environmental and public interest groups requested that EPA extend this comment period from 17 to 60 days. In their request for an extension, these groups cited a number of health issues and questions regarding interpretation of the FFDCA safety standard. EPA was not convinced that the comment period was inadequate to address the issues raised by these groups. Nonetheless, in a

Federal Register notice published on May 16, 1997 (62 FR 27002) (FRL–5719–2), EPA agreed to extend the comment period for an additional 7 days. In recognition of the cotton growers' situation, the comment period was extended to a total of 24 days rather than 60 days.

Comments in response to the proposed rule were received from public interest groups, individual concerned citizens, agricultural extension agents, representatives of state agencies, individual growers, industry groups, and Rhone Poulenc Ag Company. Responses to several of the most significant comments are presented in Unit III. of this document. Other significant comments and the Agency's responses are provided in a Response to Comments document that has been included in the docket for this action.

I. Statutory Background

Section 408 of the FFDCA, 21 U.S.C. 301 *et seq.*, as amended by the Food Quality Protection Act of 1996, (Pub. L. 104–170) authorizes the establishment of tolerances (maximum residue levels), exemptions from the requirement of a tolerance, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore ''adulterated'' under section 402(a) of the FFDCA, and hence may not legally be moved in interstate commerce. For a pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 *et seq.*).

Section 408 was substantially amended by FQPA. Among other things, the FQPA amends the 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 food, drinking water, and from pesticide use in gardens, lawns, or buildings (residential and other indoor uses) 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. . . .''

II. Final Action

The proposed rule summarizes EPA's risk assessment process, the scientific data bearing on the risk presented by bromoxynil, and EPA's assessment of the aggregate risk posed by bromoxynil. In that document, EPA concluded that there is a reasonable certainty that no harm will result to the general population and major identifiable population subgroups from aggregate exposure to bromoxynil. After reviewing all comments that were received, EPA reaffirms that conclusion today for substantially the same reasons. EPA has expanded on its basis for its conclusion in addressing significant comments.

In finalizing this rulemaking, EPA reconsidered its estimation of exposure through drinking water. Since the publication of the proposed rule, the Agency has completed a more refined (tier 2) assessment of the estimated concentration of bromoxynil residues in surface water, which can be used as an estimate of residues in surface water source drinking water. Bromoxynil residues in ground water source drinking water are expected to be negligible because bromoxynil and bromoxynil phenol degrade quickly in the environment. EPA estimated exposure in the proposal based on a modeling of potential exposure taking into account the chemical characteristics of bromoxynil octanoate. For the revised (tier 2) modeling, EPA used the chemical characteristics of bromoxynil phenol. EPA believes it is more appropriate to use the phenol because bromoxynil octanoate degrades rapidly to bromoxynil phenol, and, although both bromoxynil octanoate and bromoxynil phenol degrade rapidly, bromoxynil phenol is more persistent than bromoxynil octanoate.

The tier 2 analysis is based on the PRZM-EXAMS model (Pesticide Root Zone Model Version 2.3 plus Exposure Analysis Modeling System Version 2.94) instead of the GENEEC model (GENeric Expected Environmental Concentration) used for the tier 1 preliminary screen. PRZM-EXAMS uses data on the physical-chemical properties of the pesticide plus soil and topographic characteristics, weather data, and water quality parameters for the modeled site. PRZM-EXAMS uses this information to estimate runoff from a 10 hectare agricultural field into an immediately adjacent 1 hectare by 2 meter deep pond. PRZM-EXAMS considers reduction in dissolved pesticide concentration due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before wash off to a water body, direct deposition of spray drift into the water body, and degradation of the pesticide within the water body. PRZM-EXAMS, which was designed to estimate exposure for ecological risk assessments, tends to substantially overestimate pesticide residues in drinking water for several reasons. First, surface water source drinking water generally comes from bodies of water that are substantially larger than a 1 hectare pond. PRZM-EXAMS assumes that essentially the whole basin receives an application of the pesticide. Yet, in virtually all cases, basins large enough to support a drinking water facility will contain a substantial fraction of the area which does not receive the pesticide. Additionally, there is often at least some flow (in a river) or turn over (in a reservoir or lake) of the water so the persistence of the pesticide near the drinking water facility is usually overestimated. Second, even assuming a reservoir is directly adjacent to an agricultural field, the agricultural field may not be used to grow a crop on which the pesticide in question is registered for use. Further, the PRZM-EXAMS model does not take into account reductions in residue-loading due to applications of less than the maximum application rate or no treatment of the crop at all (percent crop treated data).

EPA has obtained sampling data from surface water that support EPA's conclusion that the 0.2 ppb (parts per billion) estimate for chronic exposure is a substantial overestimate for drinking water exposure. These data showed that approximately one percent of the samples were positive for bromoxynil with levels ranging from 0.035 ppb (level of quantification) to 6.1 ppb with the majority of samples closer to the lower end of this range. When it is considered that this sampling was conducted predominantly in locations not representative of drinking water intakes, that only a small percentage of the samples had detectable levels of bromoxynil, and that most of the samples showing bromoxynil were at levels close to or below 0.2 ppb, EPA believes that assuming 0.2 ppb for all

drinking water in the United States is a substantial overestimate.

The estimated chronic exposure level for bromoxynil in drinking water is 0.2 ppb based on the PRZM-EXAMS model; this value had previously been estimated as 0.3 ppb. In addition, the Agency has since put in place an interim policy for selection of water consumption values to be used in calculations of dietary risk; this was done in order to improve the consistency of these calculations for all Agency dietary risk analyses. Based on the estimated chronic level in drinking water of 0.2 ppb and estimated drinking water consumption of 2L by a 70 kilogram (kg) adult, carcinogenic risk is 6×10^{-7}. If the carcinogenic risk were calculated using the same water consumption value as in the proposed rule (20.9 grams/kilograms/day (g/kg/day) for the southern U.S.) and the revised chronic exposure level of 0.2 ppb, the resulting carcinogenic risk would be 4×10^{-7}.

Finally, EPA notes two corrections to the preamble of the proposed rule. First, EPA proposed to set a tolerance of 0.1 ppm for bromoxynil residues in milk. In the preamble to the proposal, EPA stated that it was proposing to increase the tolerance for bromoxynil in milk. The statement was incorrect because no milk tolerance was then in existence. The tolerance value that was proposed was accurate. Second, the preamble stated that the bromoxynil registration limits use to 3 percent of the cotton crop, or 400,000 acres. Rhone Poulenc Ag Company has applied to amend its registration to allow treatment of 400,000 acres; however, presently the application is limited to 200,000 acres. EPA plans to make a decision on that application shortly.

III. Response to Public Comments

Comments in response to the December 26, 1996 notice of filing and the May 2, 1997 proposed rule were received from several public interest groups, individual concerned citizens, agricultural extension agents, state agencies, industry groups, individual growers, and Rhone Poulenc Ag Company.

Public interest groups and individual citizens made the following comments. The commenters requested that the Agency not extend tolerances for bromoxynil on BXN cotton because: (1) Bromoxynil is a possible human carcinogen; (2) bromoxynil has caused birth defects in laboratory mammals; (3) bromoxynil is toxic to broadleaf plants and fish; (4) there are no data on bromoxynil residues on cotton fibers processed from bromoxynil-tolerant cotton; (5) expanding use of bromoxynil with a bromoxynil-tolerant crop violates the FQPA's safety standard of ''reasonable certainty of no harm from aggregate exposure''; (6) the carcinogenic risk of bromoxynil exceeds the one in a million standard of the FQPA; (7) the Agency does not have sufficient data to assess the toxicity of the metabolite DBHA.

Agricultural extension agents, representatives of state agencies, industry groups, Rhone Poulenc Ag Company, and cotton growers have requested that the Agency approve the tolerance because bromoxynil is useful to control weeds in BXN cotton. Several individuals associated with state agricultural regulatory agencies and universities have requested that the expiration date for the bromoxynil tolerance on cotton be changed from the proposed date of January 1, 1998, to January 1, 1999. The reason for this request is that commenters believe that the Agency cannot receive and analyze the results of required residue trials before January of 1999, and that having the tolerance expire before a new analysis can be conducted causes hardship for cotton growers and BXN cottonseed producers.

In this document, EPA responds to the comments concerning the level of carcinogenic risk, the available data on DBHA, and the 1 year time limitation.

1. *Cancer risk*. Various commenters argued that EPA could not make the reasonable certainty of no harm finding required by the FQPA because the aggregate cancer risk for bromoxynil exceeds 1 in 1 million. The commenters relied on legislative history from the House Commerce Committee that states that ''reasonable certainty of no harm'' for cancer risk means a risk no greater than ''negligible.'' H. Rep. 104–669, 104th Cong., 2d Sess. 44 (1996). The Committee further stated that it understood current EPA practice to be that a negligible risk is interpreted as a ''one-in-a-million lifetime risk.''

EPA believes the aggregate risk from bromoxynil meets the reasonable certainty of no harm standard. Additionally, EPA believes that the bromoxynil risk is ''negligible'' as EPA has used that term and complies with a one-in-a-million risk standard.

The lifetime dietary cancer risk (food only) for bromoxynil is 1.5 in 1 million. The lifetime cancer risk from bromoxynil residues in water is 0.6 in 1 million. Adding these risk estimates together yields an aggregate dietary risk of 2.1 in 1 million. EPA believes this risk estimate is consistent with EPA's past practice in applying a negligible risk approach. See 60 FR 3797 (2.6×10^{-6} is within negligible risk range), 59 FR 13654, 13657 (2.2×10^{-6} is within negligible risk range). EPA does not apply the negligible risk standard as a bright line test because of the lack of precision in quantitative cancer risk assessment. There are a significant number of uncertainties in both the toxicology data used to derive the cancer potency of a substance and in the data used to measure and calculate exposure. Extrapolation of results at high doses in animal studies to much lower doses in humans and from limited numbers of animals to large human populations also adds to the imprecision. Thus, with cancer risk estimates, EPA generally does not attach great significance to numerical estimates that differ by approximately a factor of 2.

In evaluating quantitative risk estimates it is also important to consider the qualitative evidence supporting the cancer assessment. EPA's Proposed Guidelines for Cancer Risk Assessment, 61 FR 17960, 17983 (April 23, 1996) (FRL–5460–3), list a series of factors to be considered in making a cancer assessment. Factors supporting a cancer classification include: (1) More than one study with consistent results; (2) same tumor site across species; (3) multiple observations across species, sites, and sexes; and (4) severity and progression of lesions including dose response relationships and rarity of tumor type. Here, bromoxynil was shown to induce liver tumors in the male mouse in two studies. Liver tumors in the female mouse was shown in one study. Bromoxynil was not shown to induce cancer in more than one species (negative in the rat) but, as indicated, did show positive results in male and female mouse in the liver. As to the severity and progression of tumors, bromoxynil appeared to have a dose response relationship in the male mouse but only induced tumors at one dose in the female. Liver tumors are common in male mice but less so in females. Finally, in the cancer studies, there was no effect from bromoxynil on survival rates, body weights, or food consumption. Bromoxynil's carcinogenicity was also supported by positive findings in three mutagenicity studies and its structural similarity to another chemical which has tested positive for carcinogenicity. While these data fully support EPA's decision to perform a quantitative cancer risk assessment, EPA would have a greater concern for the cancer risk posed by bromoxynil if, for example, a cancer response was seen in two species, the tumor involved was less common, and/

or a more severe effect was seen in treated animals.

Taking into account the quantitative cancer risk estimate, the lack of precision in quantitative cancer risk assessment, and the qualitative cancer evidence on bromoxynil, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to bromoxynil. Further, EPA is in the process of evaluating all of the bromoxynil uses this year as part of FIFRA reregistration. This will permit EPA to better evaluate the total bromoxynil cancer risk and take steps to reduce any cancer risks of concern.

2. *Data on DBHA*. Several commenters argued that the tolerance should not be granted because the Agency does not have sufficient data to assess the toxicity of the metabolite DBHA. They argued that the Agency's assumption that DBHA is equal in toxicity to bromoxynil could be wrong, that it is possible that DBHA is more toxic than bromoxynil.

EPA believes that there is little chance that DBHA would exhibit significant toxicity over that of the parent bromoxynil. Bromoxynil and DBHA are extremely similar in structure, varying only in that bromoxynil has a cyano (-CN) group that has been converted to a carboxyl (-COOH) group in the DBHA metabolite. Conversion to a carboxyl group is generally considered to decrease the toxicity of a molecule. The conversion to the carboxyl group should cause the DBHA to be more polar and therefore more soluble in water and less in fats. Additionally, the presence of the carboxyl group will allow DBHA to combine (conjugate) with certain water soluble molecules (e.g. glucuronic acid) which should further increase DBHA's water solubility and further decrease its solubility in fats. This increased water solubility as well as the decreased fat solubility means that DBHA should be eliminated faster from the organism than bromoxynil, and thus DBHA is less likely than bromoxynil to remain in the cell and engage in the formation of additional, possibly toxic metabolites.

For these reasons, EPA believes that specific toxicity data on DBHA are not needed for the safety determination on the bromoxynil tolerances.

3. *Length of tolerance*. Various growers and cottonseed producers requested that the expiration date for the bromoxynil tolerance on cotton be changed from the proposed date of January 1, 1998, to January 1, 1999. These commenters argued that the Agency cannot receive and analyze the results of required residue trials before January of 1999, and having the tolerance expire before a new analysis can be conducted causes hardship for cotton growers and BXN cottonseed producers.

The Agency proposed the January 1, 1998 expiration date because it was anticipated that the risk assessment for bromoxynil reregistration would be completed late in 1997 after this final rule was issued. EPA's reregistration decision, however, will probably not be made in time to incorporate it into a decision on a permanent tolerance if that must occur by January 1, 1998. Required residue data also will not be available for review this year. Nonetheless, EPA proposed that the tolerance only run through January 1, 1998, and this proposal had a shortened period for public comment.

EPA is willing to consider a request for an additional time extension of the bromoxynil tolerance; however, appropriate procedures must be followed. Prior to consideration of extension of the tolerance, EPA must receive a petition to request such an extension. This petition must be published, and the public given a chance to comment, before EPA can make a decision concerning the extension of this tolerance after January 1, 1998.

IV. 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(e) and (1)(6) as was provided in the old section 408 and section 409. However, the period for filing objections is 60 days rather than 30 days. EPA currently has procedural regulations which governs 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 August 18, 1997, file written objections to any aspect of this regulation and may also request a hearing with the Hearing Clerk, at the address given below (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 issue(s) on which a hearing is requested, the requestor's contentions on each such issue, and a summary of any evidence relied upon by the objector, 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 a 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 issue(s) 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 ''Confidential Business Information'' (CBI). Information marked as CBI 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.

V. Public Docket

A record has been established for this rulemaking under docket number [PP 6F4641/OPP–300486B]. 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 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #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 comments 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 a paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

VI. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and since this action does not impose any information collection requirements subject to approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of 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).

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement explaining the factual basis for this determination was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

VII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has 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 this rule in today's **Federal Register**. This 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, Food additive, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 13, 1997.

Stephen L. Johnson,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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. Section 180.324 is revised to read as follows:

§ 180.324 Bromoxynil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) resulting from application of its octanoic and/or heptanoic acid ester in or on the following commodities:

Commodity	Parts per million
Alfalfa, seeding	0.1 ppm
Barley, forage, green	0.1 ppm
Barley, grain	0.1 ppm
Barley, straw	0.1 ppm
Cattle, fat	1 ppm
Cattle, meat	0.5 ppm
Cattle, meat by-products	3 ppm
Corn, fodder (dry)	0.1 ppm
Corn, fodder (green)	0.1 ppm
Corn, fodder, field (dry)	0.1 ppm
Corn, fodder, field (green)	0.1 ppm
Corn, grain	0.1 ppm
Corn, grain, field	0.1 ppm
Eggs	0.05 ppm
Flaxseed	0.1 ppm
Flax straw	0.1 ppm
Garlic	0.1 ppm
Goats, fat	1 ppm
Goats, meat	0.5 ppm
Goats, meat by-products	3 ppm
Grass, canary, annual, seed	0.1 ppm
Grass, canary, annual, straw	0.1 ppm
Hogs, fat	1 ppm
Hogs, meat	0.5 ppm
Hogs, meat by-products	3 ppm
Horses, fat	1 ppm
Horses, meat	0.5 ppm
Horses, meat by-products	3 ppm
Milk	0.1 ppm
Mint hay	0.1 ppm
Oats, forage, green	0.1 ppm
Oats, grain	0.1 ppm
Oats, straw	0.1 ppm
Onions (dry bulb)	0.1 ppm
Poultry, fat	0.05 ppm
Poultry, meat	0.05 ppm
Poultry, meat by-products	0.05 ppm
Rye, forage, green	0.1 ppm
Rye, grain	0.1 ppm
Rye, straw	0.1 ppm
Sheep, fat	1 ppm
Sheep, meat	0.5 ppm
Sheep, meat by-products	3 ppm
Sorghum, fodder	0.1 ppm
Sorghum, forage	0.1 ppm
Sorghum, grain	0.1 ppm
Wheat, forage, green	0.1 ppm
Wheat, grain	0.1 ppm
Wheat, straw	0.1 ppm

(2) Tolerances are established for residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) and its metabolite 3,5-dibromo-4-hydroxybenzoic acid resulting from application of its octanoic and/or heptanoic acid ester in or on the following commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Cotton gin byproducts	50 ppm	1/1/1998
Cotton, hulls	21 ppm	1/1/1998
Cotton, undelinted seed	7 ppm	1/1/1998

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–15964 Filed 6-17-97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Modified base (1% annual chance) flood elevations are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATES: The effective dates for these modified base flood elevations are indicated on the following table and revise the Flood Insurance Rate Map(s) in effect for each listed community prior to this date.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Frederick H. Sharrocks, Jr., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–2796.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed