advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action proposed does not include a Federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

The Administrator's decision to approve or disapprove Pennsylvania's NSR SIP revision will be based on whether it meets the requirements of section 110(a)(2)(A)–(K) and part D of the Clean Air Act, as amended, and EPA regulations in 40 CFR Part 51.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Authority: 42 U.S.C. 7401–7671q.

Dated: April 22, 1997.

Stanley L. Laskowski,

Acting Regional Administrator, Region III.

[FR Doc. 97–11492 Filed 5–1–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[ME3–1–5258b; A–1–FRL–5815–3]

Approval and Promulgation of Redesignation; Maine; Redesignation of Millinocket to Attainment for Sulfur Dioxide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a redesignation request submitted by the State of Maine. This action redesignates Millinocket to attainment for Sulfur Dioxide (SO_2). In the Final Rules Section of this **Federal Register**, EPA is approving the State's redesignation as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this proposal. Any parties interested in commenting on this proposal should do so at this time.

DATES: Comments must be received on or before June 2, 1997.

ADDRESSES: Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystems Protection, Region I, JFK Federal Bldg., Boston, MA 02203. Copies of the State submittal and EPA's technical support document are available for public inspection during normal business hours, by appointment at the Office of Ecosystems Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 10th floor, Boston, MA and the Bureau of Air Quality Control, Department of Environmental Protection, 71 Hospital Street, Augusta, ME 04333.

FOR FURTHER INFORMATION CONTACT: Ian D. Cohen, (617) 565–3568.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

Authority: 42 U.S.C. 7401–7671q.

Dated: March 27, 1997.

John P. DeVillars,

Regional Administrator, Region I.

[FR Doc. 97–11484 Filed 5–1–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300486; FRL–5617–5]

RIN AC18

Bromoxynil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish 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-hydrobenzoic acid) resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton: undelinted cottonseed at 7 ppm, cotton gin byproducts at 50 ppm, 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 proposes to revise 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; and in milk to 0.1 ppm. Further, this document proposes to establish tolerances for residues of bromoxynil, resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton, at 0.05 ppm in eggs; and at 0.05 ppm in poultry meat, meat byproducts, and fat. EPA proposes that the tolerances for the cotton commodities expire on January 1, 1998. Rhone-Poulenc AG Co. 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.

DATES: Comments, identified by the docket control number ''OPP–300486,'' must be received on or before May 19, 1997.

ADDRESSES: By mail, submit written comments 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 comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Comments and data may also be submitted electronically by following the instructions under Unit IX. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

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) 305-5697, 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 Co., 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 Co. had submitted a pesticide petition to EPA proposing to extend the time-limited tolerance on cottonseed. The Agency is issuing this proposed rule because, after review of the petition, the Agency has 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 by-products, fat, and milk) 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, and eggs). 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, and the Environmental Defense Fund. Many of the issues raised by these comments are addressed in this document. To the extent specific comments have not been addressed herein, they will be addressed in any final action on this proposal.

I. Statutory Background

Section 408 of the Federal Food, Drug, and Cosmetic Act (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 the Food Quality Protection Act of 1996 (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. 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 effect level'' or ''NOEL'').

Once the studies have 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. 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. For threshold effects other than those assessed under the RfD, EPA generally calculates a margin of exposure (MOE). The MOE is a measure of how close the exposure comes to the NOEL. The NOEL is selected from a study of appropriate duration and route of exposure. The MOE is the NOEL from the selected study divided by exposure. MOEs greater than 100 are generally considered to show 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 calculation 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 and exposures resulting from indoor and outdoor residential uses. 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 which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

III. Toxicology Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Bromoxynil is applied to crops in the form of bromoxynil octanoate and bromoxynil heptanoate. These starting materials are metabolized to bromoxynil phenol. The nature of the toxic effects caused by bromoxynil is discussed below.

A. Phenol Technical-grade Bromoxynil

1. Several acute toxicity studies were performed, placing technical-grade bromoxynil in Toxicity Category II.

2. An acute oral toxicity study in rats resulted in LD_{50}=81 milligrams/kilograms (mg/kg) (males) and 93 mg/kg (females).

3. A 2–year combined feeding/carcinogenicity study was conducted with rats administered (oral) dosages of 0, 60, 190, or 600 parts per million (ppm) (0, 2.6, 8.2, or 28 mg/kg/day in males; 0, 3.3, 11.0, or 41 mg/kg/day in females) bromoxynil phenol in the diet. In males, the NOEL is 2.6 mg/kg/day, and the lowest-effect-level (LEL) is 8.2 mg/kg/day. In females, the NOEL is 3.3 mg/kg/day, and the LEL is 11.0 mg/kg/day. This study did not demonstrate any increase in tumor incidences in either male or female rats.

4. A 120–week combined feeding/carcinogenicity study was conducted with rats administered bromoxynil phenol in the diet at dose levels of 0, 10, 30, or 100 ppm (0, 0.5, 1.5, or 5 mg/kg/day). In both males and females, the NOEL and LEL was 5 mg/kg/day and >5 mg/kg/day, respectively. This study was negative for carcinogenicity. This study is considered supplementary.

5. A 1–year chronic oral study was conducted with dogs administered bromoxynil phenol at dose levels of 0, 0.1, 0.3, 1.5, or 7.5 mg/kg/day in capsules. A threshold NOEL/LOEL of 1.5 mg/kg/day was determined in this study based on slightly decreased body weight gain in males. At 7.5 mg/kg/day, additional toxic effects were observed in both males and females. The RfD is based on this study.

6. An 18–month carcinogenicity study was conducted with mice administered bromoxynil phenol at dose levels of 0, 10, 30, or 100 ppm (0, 1.3, 3.9, or 13 mg/kg/day) in the diet. For males, dose-related increases in hyperplastic nodules and liver adenomas/carcinomas were observed which were statistically significant at the 13 mg/kg/day dose level. Increased relative liver weights were also observed at 13 mg/kg/day. In females, increased absolute kidney weights and relative liver and kidney weights were observed at 13 mg/kg/day. The study was negative for carcinogenicity for females, but the doses were considered to be not high enough.

7. An 18–month carcinogenicity study was conducted with mice administered bromoxynil phenol in the diet at dose levels of 0, 20, 75, or 300 ppm (0, 3.1, 12, or 46 mg/kg/day in males; 0, 3.7, 14, or 53 mg/kg/day in females). In males, treatment-related increases in liver adenomas/carcinomas were observed at all dose levels. At 12 mg/kg/day and higher in males, gross pathologic and histopathologic effects were also noted in the liver. In females, treatment-related increases in liver carcinomas were observed at 53 mg/kg/day. At 14 mg/kg/day and higher in females, histopathologic effects were also noted in the liver. The results of this study are discussed more fully in Unit IV. of this preamble addressing carcinogenicity classification.

8. A developmental toxicity study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0, 4, 12.5, or 40 mg/kg/day. The maternal NOEL and LEL are 12.5 mg/kg/day and 40 mg/kg/day, respectively. The developmental NOEL and LEL are 4 mg/kg/day and 12.5 mg/kg/day, respectively, based on increased incidence of supernumerary ribs.

9. A developmental toxicity study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0, 5, 15, or 35 mg/kg/day. The maternal NOEL and LEL are 5 mg/kg/day and 15 mg/kg/day, respectively. The developmental NOEL and LEL are less than 5 mg/kg/day and 5 mg/kg/day, respectively, based on increased incidence of supernumerary ribs.

10. A developmental toxicity study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0, 1.7, 5, or 15 mg/kg/day. The maternal NOEL and LEL are 5 mg/kg/day and 15 mg/kg/day, respectively. The developmental NOEL and LEL are 5 mg/kg/day and 15 mg/kg/day, respectively, based on increased incidence of supernumerary ribs.

11. A developmental toxicity study was conducted with rabbits administered (orally) bromoxynil phenol at dose levels of 0, 15, 30, or 60 mg/kg/day. The maternal NOEL and LEL are 15 mg/kg/day and 30 mg/kg/day, respectively. The developmental NOEL and LEL are <15 mg/kg/day and 15 mg/kg/day, respectively, based on increased incidence of supernumerary ribs.

12. A developmental toxicity study was conducted with rabbits administered (orally) bromoxynil phenol at dose levels of 0, 30, 45, or 60 mg/kg/day. The maternal NOEL and LEL are 45 mg/kg/day and 60 mg/kg/day, respectively. The developmental NOEL and LEL are <30 mg/kg/day and 30 mg/kg/day, respectively, based on decreased fetal weights.

13. A developmental toxicity study was conducted with mice administered (orally) bromoxynil phenol at dose levels of 0, 11, 32, or 96 mg/kg/day. The maternal NOEL and LEL are 11 mg/kg/day and 32 mg/kg/day, respectively. The developmental NOEL and LEL are 32 mg/kg/day and 96 mg/kg/day, respectively, based on increased supernumerary ribs, decreased fetal weights, and unossified caudal vertebrae.

14. A reproduction study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0, 10, 50, or 250 ppm (0, 0.8, 4, or 21 mg/kg/day) in the diet for 2 generations. The systematic adult rat NOEL is 4 mg/kg/day, and the LEL is 21 mg/kg/day. The reproductive NOEL is 21 mg/kg/day, and the LEL is >21 mg/kg/day. The postnatal development NOEL is 4 mg/kg/day, and the LEL is 21 mg/kg/day.

15. A reproduction study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0, 30, 100, or 300 ppm (0, 1.5, 5, or 15 mg/kg/day) in the diet for 3 generations. The systemic adult rat NOEL is 1.5 mg/kg/day, and the LEL is 5 mg/kg/day. The reproductive NOEL is 15 mg/kg/day, and the LEL is >15 mg/kg/day. The offspring developmental NOEL is 5 mg/kg/day, and the LEL is 15 mg/kg/day. All the NOELs and LELs in this study are considered to be tentative.

16. Mutagenicity data included an unscheduled DNA synthesis study in rat primary hepatocytes (negative); an *in vitro* transformation assay in mouse cells (negative); a sister chromosomal

exchange study in CHO cells (negative); a forward mutation study in mouse lymphoma cells (negative without activation and positive with activation); a DNA repair test in *E. coli* (positive without and with activation); an *in vitro* chromosomal aberration assay in CHO cells (negative without activation and positive with activation); two separate micronucleus assays in mice (both negative); a forward mutation assay in CHO cells (negative); and an Ames study in *Salmonella typhimurium* (negative with and without activation).

B. Heptanoate Technical-grade Bromoxynil

1. Several acute toxicity studies were performed, placing technical-grade bromoxynil heptanoate in Toxicity Category II.

2. An acute oral toxicity study in rats resulted in LD_{50}=362 mg/kg (males) and LD_{50}=292 mg/kg (females).

3. A general metabolism study was conducted with rats. Bromoxynil heptanoate is rapidly absorbed and widely distributed in most tissues. Most of the radioactivity was excreted in the urine, mostly in the form of bromoxynil phenol. There was no significant retention in tissues after 7 days. Essentially, bromoxynil heptanoate was metabolized to bromoxynil phenol via ester hydrolysis.

C. Octanoate Technical-grade Bromoxynil

1. Several acute toxicity studies were performed, placing technical-grade bromoxynil octanoate in Toxicity Category II.

2. An acute oral toxicity study in rats resulted in LD_{50}=400 mg/kg (males) and LD_{50}=238 mg/kg (females).

3. A 13-week oral study was conducted with rats administered bromoxynil octanoate at dose levels of 0, 150, 600, or 1,100 ppm (0, 11, 45, or 91 mg/kg/day in males; 0, 13, 55, or 111 mg/kg/day in females) in the diet. In males, the NOEL and LEL are 45 mg/kg/day and 91 mg/kg/day, respectively. In females, the NOEL and LEL are 13 mg/kg/day and 55 mg/kg/day, respectively.

4. A 13-week oral study was conducted with dogs administered bromoxynil octanoate in capsules at dose levels of 0, 0.43, 1.43, or 7.14 mg/kg/day. In males and females, the NOEL and LEL are 0.43 mg/kg/day and 1.43 mg/kg/day, respectively.

5. A developmental toxicity study was conducted with rats administered (orally) bromoxynil octanoate at dose levels of 0, 2.4, 7.3, or 21.8 mg/kg/day. The maternal NOEL and LEL are 7.3 mg/kg/day and 21.8 mg/kg/day, respectively. The developmental NOEL and LEL are 7.3 mg/kg/day and 21.8 mg/kg/day, respectively, based on increased supernumerary ribs and decreased fetal weights.

6. Mutagenicity data included the following: an Ames study in *Salmonella typhimurium* (negative with and without activation); a micronucleus assay in mice (negative); and an unscheduled DNA synthesis study in rat primary hepatocytes (negative).

7. A general metabolism study was conducted with rats. Bromoxynil octanoate is rapidly absorbed and widely distributed in most tissues. Most of the radioactivity was excreted in the urine, mostly in the form of bromoxynil phenol. There was no significant retention in tissues after 7 days. Essentially, bromoxynil octanoate was metabolized to bromoxynil phenol via ester hydrolysis.

IV. Dose Response Assessment

1. *Carcinogenicity classification*. Using EPA's ''Guidelines for Carcinogen Risk Assessment'' published September 24, 1986 (51 FR 33992), EPA has classified bromoxynil as a Group ''C'', possible human carcinogen, with a Q1* for bromoxynil phenol of 1.03×10^{-1} $(mg/kg/day)^{-1}$. This classification was based primarily on results in two mouse carcinogenicity studies. In one study, a statistically significant increase in and combined liver adenomas/carcinomas was observed in male mice at the highest dose tested. For carcinomas, there was not a statistically significant increase at any dose. A statistically significant increased incidence of neoplasms was not observed in female mice, but the doses for females were determined to be inadequate. In another study, a statistically significant increased incidence of combined liver adenomas/carcinomas was observed in male mice at all dose levels and in female mice at the highest dose. For carcinomas, the male mice had a statistically significant increase at the high and low dose (but not the mid-dose) and the females had a statistically significant increase at the high dose. Following a second pathology examination of the male mice, the results were a statistically significant increase at the low and high doses for combined adenomas/carcinomas and for carcinomas a statistically significant increase at the high dose. Bromoxynil was not carcinogenic in the rat. Information from the mutagenicity studies, which included three positive studies, provided additional support for the ''C'' classification.

2. *Reference Dose* (Rfd). For systemic effects other than cancer, the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The RfD is determined using the toxicological end-point or NOEL from the most sensitive mammalian toxicological study. To assure the adequacy of the RfD, the Agency uses an uncertainty factor in deriving it. The RfD for bromoxynil is 0.015 mg/kg/day based on the threshold NOEL/LOEL of 1.5 mg/kg/day determined in the 1-year chronic oral study in dogs using bromoxynil phenol as the test material. An uncertainty factor of 100 was used for interspecies extrapolation and intraspecies variability.

3. *Developmental toxicant determination*. Bromoxynil phenol and bromoxynil octanoate both induce developmental toxicity at levels below those which cause maternal toxicity. The induction of supernumerary ribs is the most sensitive indicator of developmental toxicity in rats, mice and in certain studies in rabbits. Other forms of developmental toxicity are observed at higher dose levels.

4. *Acute risk/developmental effects*. For acute dietary risk assessment, EPA has chosen to use the NOEL of 4 mg/kg/day, based on developmental effects in an oral rat developmental toxicity study (MRID # 40466802) at the LOEL of 5 mg/kg/day from a second oral rat developmental toxicity study (MRID # 00116558). Since the effect of concern, increased incidence of supernumerary ribs in fetuses, occurs in utero during gestation, this risk assessment is only directly applicable to females of child-bearing age (population sub-group of females 13+ yrs old).

5. *Acute risk/systemic effects other than developmental.* EPA has concluded that an additional endpoint of concern should be established for assessing the acute dietary risk for bromoxynil exposure to population groups (including infants and children) other than females 13+ years. Acute (one-day) dietary exposure estimates will be compared to an endpoint (NOEL) of 8 mg/kg/day derived from the data of a 13-week oral toxicity study in dogs using bromoxynil phenol as the test material (MRID 43166701). The LOEL was established at 12 mg/kg/day, based on increased incidence of panting on day 1 following a single oral dose of the test material. This suggests a compensatory reaction to the effects of the test material, which at higher doses is expressed as elevated body temperature.

V. Aggregate Exposure Assessment

In examining aggregate exposure, FFDCA section 408(b)(2) directs EPA to

consider available information concerning exposures from pesticide residue in food, water, and all other nonoccupational exposures. The aggregate sources of exposure the Agency looks at includes food, drinking water (which includes both surface water and groundwater), and exposure from pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Non-dietary (Residential) Exposure Assessment

Currently, there are no registered homeowner uses for bromoxynil and current labeling restricts all turfgrass use to non-residential areas. The possibility of post-application exposure to persons following bromoxynil application to nonresidential turfgrass exists, but is not likely to be significant in either amount or duration (and cannot be quantified at this point).

B. Dietary Exposure Assessment

Use of a agricultural pesticide may result, directly or indirectly, in pesticide residues in food. Primary residues or indirect/inadvertent residues in agricultural commodities are determined by chemical analysis. To account for the diversity of growing conditions, cultural practices, soil types, climates, crop varieties and methods of application of the pesticide, data from studies that represent the commodities are collected and evaluated to determine an appropriate level of residue that would not be exceeded if the pesticide is used as represented in the studies. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

1. *Plant/animal metabolism and magnitude of the residue tolerance assessment.* The nature (metabolism) of bromoxynil in plants and animals is adequately understood for the purposes of these tolerances. There are no Codex, Canadian, or Mexican maximum residue levels established for residues of bromoxynil on cotton. In all the plant and animal (poultry and ruminants) metabolism studies submitted, the residue of concern were parent bromoxynil and the metabolite DBHA. The tolerances for cotton commodities are expressed in terms of bromoxynil and DBHA. Tolerances for meat and milk commodities, however, are expressed only in terms of bromoxynil because no satisfactory enforcement method has been validated for DBHA in such commodities. Transfer of DBHA residues to tissues in animals is likely to be equal to or less than that for parent bromoxynil. Based on this determination, coupled with worst-case assumptions concerning the amount of bromoxynil and DBHA present in animal feed, the Agency can make reasonable estimates of maximum DBHA concentrations in animal commodities based on measured parent bromoxynil residues. Therefore, the Agency has determined that expressing tolerances for bromoxynil in terms of the parent only can serve as an adequate indicator of the total amount of residue (bromoxynil parent and DBHA combined) that is present.

Although the maximum application rate for this use is 1.5 lb active ingredient/acre (ai/acre), field trial residue data are currently available only for a 4.5 lb ai/acre application rate. After conducting these studies, the petitioner proposed lowering the maximum application rate from 4.5 lb ai/acre to 1.5 lb ai/acre. These tolerances were determined based on extrapolation of data from studies conducted using the 4.5 lb ai/acre application rate. The Agency does not believe that there will necessarily be a linear relationship between maximum residues and the application rate due to the variability in residue levels in individual commodities. However, at the 1.5 lb ai/acre rate, lower maximum residues would be expected compared to those observed in the studies conducted at 4.5 lb ai/acre. The Agency has determined the required tolerances for this use based on the variability observed in the available residue data for cotton and the reduction in the application rate. EPA is proposing to include a tolerance for cotton gin byproducts, although this was not done previously, because EPA procedures have been revised since the previous tolerance was set to include cotton gin byproducts in the dietary assessment for livestock. In addition, a separate tolerance is being set for cottonseed hulls because data show that bromoxynil and DBHA residues concentrate in cottonseed hulls. Further, because of the inclusion of cotton gin trash in the livestock dietary assessment, revised tolerances are needed for milk and meat of cattle, hogs, horses, goats and sheep. Inclusion of the metabolite DBHA in the livestock dietary assessment also resulted in the need to establish tolerances for bromoxynil residues in poultry. Required tolerances for residues of bromoxynil and DBHA in cotton commodities are 7 ppm in cottonseed, 50 ppm in cotton gin by-products, and 21 ppm in cottonseed hulls. Required tolerances for residues of bromoxynil in cattle, hogs, horses, goats, and sheep are 0.5 ppm in meat, 3.0 ppm in meat byproducts, and 1.0 ppm in fat. Required tolerances for residues of bromoxynil in milk are 0.1 ppm. Required tolerances for residues of bromoxynil in poultry are 0.05 ppm in meat, meat-byproducts, fat, and eggs.

2. *Plant/animal metabolism and magnitude of the residue determination of anticipated residues.* Anticipated residues used for risk assessment determination were calculated based on a maximum application rate of 1.5 lb ai/acre and treatment of 3 percent of cotton in the U.S. with bromoxynil, and estimated bromoxynil-treated percentages of other crops. Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using the upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. For cotton, the percent of the crop that can be treated will be capped at 3 percent by the bromoxynils registration. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations, including several regional groups, to pesticide residues. As a result of this use, the maximum combined residues of parent bromoxynil and DBHA are not expected to exceed 0.38 ppm in cottonseed meal and 1.26 ppm in cottonseed oil. Based on the bromoxynil ruminant feeding study, the maximum residues possible in animal commodities are 0.53 ppm in meat, 2.96 ppm in meat byproducts, 1.08 ppm in fat, and 0.059 ppm in milk. Based on the bromoxynil poultry feeding study, the maximum residues possible in poultry commodities are 0.064 ppm in meat, 0.47 ppm in meat by-products, 0.10 ppm in fat, and 0.0313 ppm in eggs. Based on the bromoxynil ruminant feeding study, the anticipated residues in animal commodities are 0.0025 ppm in meat, 0.014 ppm in meat by-products, 0.005 ppm in fat, and 0.00044 ppm in milk. Based on the bromoxynil poultry feeding study, the anticipated residues in poultry commodities are 0.00015 ppm in meat, 0.00116 ppm in meat by-products, 0.00025 ppm in fat, and 0.00008 ppm in eggs.

3. *Drinking water.* Available data indicate that bromoxynil is not a groundwater contaminant because it does not exhibit the mobility or persistence characteristics of pesticides that are normally found in ground water. Although bromoxynil octanoate

has been found to be mobile under certain conditions (sand, sandy loam, and loam soils), it dissipates in the environment by abiotic hydrolysis, photodegradation and microbially-mediated metabolism. Also, although bromoxynil has the potential to leach to ground water under certain conditions, its rapid aerobic and anaerobic degradation reduces the likelihood of ground water contamination. As a worst-case screen, modeled chronic and acute estimates for bromoxynil in runoff water have been used to assess possible exposure via drinking water. The EPA drinking water risk estimates are based on an exposure modeling procedure called GENEEC (GENeric Expected Environmental Concentration), routinely used to estimate residue surface water runoff (for ecological risk assessment) but a new tool for human exposure and risk assessment. GENEEC estimates concentrations based on a few basic chemical parameters and pesticide label application information. GENEEC is a model which uses a chemical's soil/water partition coefficient and degradation half-life values to estimate runoff from a 10 hectare agricultural field into a 1 hectare by 2 meter deep pond. GENEEC 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. It does not consider the potential reduction or removal of the pesticide and/or its degradates by a drinking water treatment system. Again, GENEEC should be considered a screen since it can substantially over-estimate the actual drinking water concentrations. Based on the model, EPA estimated the high-end level of exposure in surface water to be 7.2 ppb, and the average level to 0.3 ppb. For analysis of acute risk, EPA used high end consumption estimates from the publication Total Water and Tapwater Intake in the United States Population-Based Estimates of Quantities and Sources of 40.5 g/kg/day for the entire U.S. population, 126.5 g/kg/day for nonnursing infants, 39.6 g/kg/day for pregnant women (>13 years old), and 53.3 g/kg/day for the southern U.S. For analysis of chronic risk, EPA used an average consumption estimate from this publication of 20.9 g/kg/day for the southern U.S. The estimate for water consumption in the southern U.S. was used for the chronic risk assessment because this value is slightly higher than that for the entire U.S. population, and, therefore, calculation based on consumption in the southern U.S. adequately accounts for risk in the south as well as the overall U.S. population.

3. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may be helpful in determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodology to 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 examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although, at present, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanisms issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether bromoxynil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach, bromoxynil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that bromoxynil has a common mechanism of toxicity with other substances. After EPA develops methodologies for more fully applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier.

The registrant must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether bromoxynil shares a common mechanism of toxicity with any other substance and, if so, whether any tolerance for bromoxynil needs to be modified or revoked.

VI. Determination of Safety

A. General

1. *Acute dietary.* As part of the hazard assessment process, the Agency reviews the available toxicology data base to determine the endpoints of concern. For acute dietary risk, the Agency has determined Margin of Exposure (MOE) by dividing the NOEL from the relevant toxicological study by the expected consumption during one day (MOE = NOEL/exposure). An estimated MOE of 100 will be considered to be adequately protective for bromoxynil. To estimate acute dietary risk for developmental effects from food sources, an MOE of 400 was calculated using 1-day dietary exposure estimates for U.S women (age 13+ years) and the NOEL of 4 mg/kg/day derived from an oral developmental toxicity study in rats. To estimate acute dietary risk for developmental effects from water sources, an MOE of >10,000 was calculated using an estimate of 7.2 parts per billion (ppb) water contamination and the endpoint (NOEL) of 4 mg/kg/day. An increased incidence of supernumerary ribs was observed at the LEL in the oral developmental toxicity study in rats and in several other developmental toxicity studies. To estimate acute dietary risk for systemic effects, other than developmental from food sources, an MOE of 270 was calculated using 1-day dietary exposure for infants (the most highly exposed population group) and a NOEL of 8 mg/kg/day derived from a 13-week oral

toxicity study in dogs. To estimate acute dietary risk for systemic effects, other than developmental from water sources, an MOE of >8,000 was calculated using an estimate of 7.2 ppb water contamination and a NOEL of 8 mg/kg/day. In the oral toxicity study in dogs, an increased incidence of panting, suggestive of a compensatory reaction to elevated body temperatures, was observed on day 1.

An assessment of aggregate (food/water) acute exposure has been made on the assumption of a constant background contamination level in water and an acute (one day) exposure from food sources. The relatively low level of contamination assumed for water does not significantly increase the upper-bound exposure estimate from foods of 0.01 mg/kg/day (MOE = 400 for U.S. women).

2. *Chronic dietary*. Based on the exposure assessment above, the general U.S. population and all population subgroups are estimated to be exposed at a level less than 1 percent of the bromoxynil RfD of 0.015 mg/kg/day. For food sources, the lifetime upperbound carcinogenic risk estimate including cotton is 1.5×10^{-6} for the U.S. population including infants and children. For water sources, carcinogenic risk, based on the estimated chronic level of 0.3 ppb and estimated drinking water consumption (20.9 g/kg/day for the southern U.S.) is at most 6.3×10^{-7} for the southern U.S., and is probably much lower.

EPA believes that a risk estimate of this level generally represents a negligible risk, as EPA has traditionally applied that concept. EPA has commonly referred to a negligible risk as one that is at or below 1 in 1 million (1×10^{-6}). Quantitative cancer risk assessment is not a precise science. There are a significant number of uncertainties in both the toxicology used to derive the cancer potency of a substance and in the data used to measure and calculate exposure. Thus, EPA generally does not attach great significance to numerical estimates that differ by approximately a factor of 2. Additionally, there are several other factors here which support a negligible risk finding. The component of this risk from bromoxynil residues in water (6.3×10^{-7}) is significantly overstated. The level of bromoxynil residues in water was estimated by a model that does not take into account either the reduction that could be expected from treatment of the water or that residues would be reduced because bromoxynil use is permitted only on certain crops and only some fraction of those crops would be treated. This latter factor alone can be quite significant. For example, for cotton, treatment is limited to 3 percent of the crop. Further, EPA is in the process of reevaluating all of the bromoxynil uses this year as a 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. For all of these reasons, EPA considers the carcinogenic risk from bromoxynil to be negligible within the meaning of that standard as it has been traditionally applied by EPA.

Accordingly, EPA concludes 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. Specific risks to infants and children other than cancer are discussed below.

B. Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of bromoxynil, EPA considered data from several developmental toxicity studies and reproduction studies. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional 10–fold margin of safety 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 determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOEL in the animal study appropriate to the particular risk assessment. This 100-fold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard 100-fold margin/factor and not the additional 10–fold margin/factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor.

The data base for developmental and reproductive toxicity of bromoxynil is considered to be complete at this time. Based on this database, EPA has concluded that, although developmental toxicity was observed in the absence of maternal toxicity, the results of these data did not raise concerns regarding the adequacy of the standard margin of exposure. Central to this conclusion were the findings that: (1) Developmental toxicity was well-characterized in multiple species, providing a reliable NOEL, and further studies would not be expected to provide new information that would change the developmental endpoints on which bromoxynil is regulated; and (2) the observed developmental effect (supernumerary ribs) raised no unusual or special concern for developmental toxicity.

Accordingly, EPA concludes that reliable data support reliance upon the standard 100-fold margin of exposure/safety factor in assessing the risk to children. As detailed above, both chronic and acute assessments show no appreciable threshold risks to children and the non-threshold cancer risk is no greater than negligible. Thus, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to bromoxynil.

VII. Other Considerations

1. *Residue analytical methods*. Analytical methodology suitable for the enforcement of bromoxynil tolerances in plant and animal commodities is available. The analytical method for bromoxynil per se is published as Method I in *Pesticide Analytical Manual Vol. II.* Method RES9603 has been proposed for determination of DBHA in cotton RACs. This analytical method for determination of DBHA in plants has been validated by an independent laboratory. The Agency is currently carrying out confirmatory validation of this method.

2. *Endocrine effects*. Existing data do not support a conclusion that bromoxynil causes endocrine effects. Other than equivocal effects in the prostate gland of dogs at the highest dose tested in a chronic oral study and in the prostate gland of rats at the highest dose tested in a dermal reproduction study, no evidence of endocrine effects were reported in any other subchronic or chronic toxicology

studies on bromoxynil phenol or bromoxynil octanoate.

3. *Data gaps*. The following data gaps remain for use of bromoxynil on BXN cotton: (1) DBHA storage stability data, (2) successful petition method validation (i.e., method validation by Agency analytical chemists) of the enforcement method for DBHA in plants, (3) multi-residue method testing for DBHA, (4) limited field trials for rotational crops, (5) a poultry feeding study using DBHA, and (6) crop field trials, conducted at the 1.5 lb ai/acre application rate, in which the magnitude of residues is measured in cotton commodities.

VIII. Public Comment

Under FFDCA 408(e)(2), EPA must provide for a public comment period before issuing a final tolerance or tolerance exemption under 408(e)(1). The public comment period is to be for 60 days unless EPA for good cause finds that it is in the public interest to reduce that comment period. The Agency has determined that there is good cause to reduce the comment period for these tolerances. First, the public has already had an opportunity to comment on the question of approval under the FFDCA of the use of bromoxynil on cotton. The Rhone Poulenc petition to establish a tolerance to cover bromoxynil residues on cottonseed resulting from application of bromoxynil to cotton squarely presented this issue. Second, the additional comment period is being provided to address a fairly narrow issue: what should the tolerance levels be for bromoxynil on livestock commodities (meat, milk, and eggs) due to residues of bromoxynil in cotton livestock feed commodities and what should the tolerance level be on two additional cotton livestock feed commodities (cotton gin byproducts and cottonseed hulls). All of these tolerance levels are necessary because of the use of bromoxynil on cotton, the subject of the Rhone Poulenc petition. Third, an extended comment period in this case will essentially mean that bromoxynil will not be available to growers in the 1997 growing season. The time for application of this herbicide is between roughly the end of April and the end of June. Growers who have paid a premium for bromoxynil-resistant seed may suffer consider financial loss if bromoxynil is not available. EPA would like to be in a position to make a final decision prior to the end of that period. Therefore, the Agency is allowing a 15–day instead of a 60–day public comment period for these proposed tolerances.

Interested persons are invited to submit written comments on this proposed regulation. Comments must bear a notation indicating the docket control number ''OPP–300486.''

IX. Public Docket

The official record for this proposed rule, as well as the public version, has been established for this proposal under docket control number ''OPP–300486'' (including comments and data submitted electronically as described below). 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 official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number OPP–300486. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

X. 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).

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: April 28, 1997.

Jim Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

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, meat	0.5 ppm
Cattle, meat by-products	3 ppm
Cattle, fat	1 ppm
Corn, fodder (dry)	0.1 ppm
Corn, fodder (green)	0.1 ppm
Corn, grain	0.1 ppm
Corn, fodder, field (dry)	0.1 ppm
Corn, fodder, field (green)	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, meat	0.5 ppm
Goats, meat by-products	3 ppm
Goats, fat	1 ppm
Grass, canary, annual, seed	0.1 ppm
Grass, canary, annual, straw	0.1 ppm
Hogs, meat	0.5 ppm
Hogs, meat by-products	3 ppm
Hogs, fat	1 ppm
Horses, meat	0.5 ppm
Horses, meat by-products	3 ppm
Horses, fat	1 ppm
Milk	0.1 ppm
Mint hay	0.1 ppm
Oats, forage, green	0.1 ppm
Oats, grain	0.1 ppm

Commodity	Parts per million
Oats, straw	0.1 ppm
Onions (dry bulb)	0.1 ppm
Poultry, meat	0.05 ppm
Poultry, meat by-products	0.05 ppm
Poultry, fat	0.05 ppm
Rye, forage, green	0.1 ppm
Rye, grain	0.1 ppm
Rye, straw	0.1 ppm
Sheep, meat	0.5 ppm
Sheep, meat by-products	3 ppm
Sheep, fat	1 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, undelinted seed	7 ppm	1/1/1998
Cotton, hulls	21 ppm	1/1/1998
Cotton gin byprod-ucts	50 ppm	1/1/1998

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

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

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

[FR Doc. 97–11504 Filed 5–01–97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket No. 95–91; GEN Docket No. 90–357; DA 97–908]

Satellite Digital Audio Radio Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension to file comments.

SUMMARY: The Commission has adopted an *Order* granting an extension of time in which to file comments in the Commission's Further Notice of Proposed Rulemaking in IB Docket No. 95–91. On April 30, 1997, the National Association of Broadcasters requested a thirty-day extension of time to file comments in the FNPRM. In the *Order,* we grant NAB's request and extend the comment and reply dates to June 13 and June 27, 1997, respectively.

DATES: Comments are due on or before June 13, 1997. Reply comments are due on or before June 27, 1997.

ADDRESSES: Office of the Secretary, Federal Communications Commission, 1919 M Street, N.W., Room 222, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Rosalee Chiara at (202) 418–0754 or Ron Repasi at (202) 418–0768 with the International Bureau.

SUPPLEMENTARY INFORMATION:

1. The National Association of Broadcasters (NAB) has requested an extension of time for filing comments in response to the Further Notice of Proposed Rulemaking in the above captioned docket regarding the use of terrestrial repeaters in the satellite Digital Audio Radio Service (DARS).[1] Comments were originally due on May 2, 1997. We grant NAB's request.

2. In support of its request for additional time, NAB states that the two DARS applicants who won licensees in the April auction are required to submit amended technical proposals on or before May 16. NAB asserts that it is impossible to comment on the issue of terrestrial repeaters until this amended technical information is available. NAB also states that because the applicant's original applications were filed in 1992, up-to-date technical proposals are necessary to prepare comments.

3. We find that an extension is warranted in this instance. Accordingly, pursuant to Section 0.261 of the Commission's rules on delegation of authority, 47 CFR § 0.261, IT IS ORDERED, that the time for filing comments with respect to the Further Notice of Proposed Rulemaking in this proceeding is extended to June 13, 1997. Reply comments are due on or before June 27, 1997.

Federal Communications Commission.

Cassandra Thomas,

Deputy Chief, Satellite and Radiocommunication Division, International Bureau.

[FR Doc. 97–11678 Filed 5–1–97; 8:45 am]

BILLING CODE 6712–01–P

[1] Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310–2360 MHz Frequency Band, IB Docket No. 95–91, 62 FR 19095 (April 18, 1997), FCC 97–70 (released March 3, 1997) at ¶¶138–142.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[I.D. 042497A]

New England Fishery Management Council; Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Public meeting.

SUMMARY: The New England Fishery Management Council (Council) will hold a special public meeting to consider actions affecting New England fisheries in the exclusive economic zone.

DATES: The meeting will be held on Tuesday, May 6, 1997, at 9:30 a.m.

ADDRESSES: The meeting will take place at the Holiday Inn, 1 Newbury Street (Route 1), Peabody, MA; telephone (508) 535-4600. Requests for special accommodations should be addressed to the New England Fishery Management Council, 5 Broadway, Saugus, MA 01906-1036; telephone (617) 231-0422.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council, (617) 231-0422.

SUPPLEMENTARY INFORMATION: On May 6, 1997, the Council will convene a special meeting specifically to develop comments on the Large Whale Take Reduction Plan regulations recently proposed by NMFS. Prior to this agenda item, the Council intends to initiate action on Framework Adjustment 24 to the Northeast Multispecies Fishery Management Plan under the framework for abbreviated rulemaking procedure contained in 50 CFR 648.90. The action would exempt gillnet vessels in the trip boat category from the requirement to bring their monkfish gillnets to port when fishing under a days-at-sea allocation.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*