* * * * *

[FR Doc. 2011–13587 Filed 5–31–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0268; FRL–8873–9]

Bromoxynil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises established tolerances for residues of bromoxynil in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 1, 2011. Objections and requests for hearings must be received on or before August 1, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0268. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0268 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 1, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0268, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 23, 2010 (75 FR 35801) (FRL–8831–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7678) by Bayer CropScience LLC, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.324 be amended by increasing existing tolerances for residues of the herbicide bromoxynil, 3,5-dibromo-4-hydroxybenzonitrile, in or on sorghum, grain, grain from 0.05 parts per million (ppm) to 0.2 ppm; grass, hay from 3.0 ppm to 5.0 ppm; and grass, forage from 3.0 ppm to 18 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has determined that the existing tolerances for aspirated grain fractions, milk, and grain sorghum forage must also be increased as a result of the proposed changes to the use patterns for sorghum and grasses. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA 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 * * *."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for bromoxynil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bromoxynil follows.

A. Toxicological 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 phenol has moderate acute toxicity via the oral and inhalation routes of exposure and low acute toxicity via the dermal route. Bromoxynil octanoate has moderate acute toxicity via the oral and dermal routes and low acute toxicity via the inhalation route. Due to rapid conversion of the ester forms of the chemical (heptanoate and octanoate) to the phenol, toxicity testing was conducted with both phenol and octanoate material, but the risk assessment is based on exposure to the phenol.

In the repeated dose studies of the mammalian toxicology database, the liver was the primary target organ of bromoxynil toxicity. Across species, duration and gender, changes in weight, clinical chemistry and pathology indicated treatment-related perturbations in and adverse effects on liver function. Treatment-related effects were also observed on body weight and body weight gain in rats, mice, dogs, and rabbits. Subchronic and chronic studies in dogs showed that bromoxynil elevated body temperature, manifested by increased panting at lower dose levels, and hyperthermia and death as dose levels increased.

Developmental toxicity was manifested in rats, mice and rabbits via the oral and dermal routes by increased incidence of supernumerary (13th and/or 14th) ribs at dose levels as low as 5 milligrams/kilogram/day (mg/kg/day) in rats. At higher dose levels, malformations such as hydrocephalus, enophthalmia, micropthalmia, fused ribs, scoliosis, misshapen thoracic centrum and incomplete ossification of sternebrae were observed in rabbits. In reproduction studies, delayed development manifested as decreased body weight and body weight gain, and delayed eye opening.

Bromoxynil is classified as a "possible human carcinogen" based on the presence of hepatocellular tumors in male and female mice. There is no concern for mutagenicity. The method of quantification of cancer risk is linear, using the cancer slope factor (Q*) of 0.103 $(mg/kg/day)^{-1}$ in human equivalents.

Specific information on the studies received and the nature of the adverse effects caused by bromoxynil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Bromoxynil: Human Health Risk Assessment for Amended Uses on Grass Grown for Seed, Conservation Reserve Program Areas, and Grain Sorghum," p. 50 in docket ID number EPA–HQ–OPP–2010–0268.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) (a = acute and c = chronic) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for bromoxynil used for human risk assessment is shown in the following table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BROMOXYNIL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary ..... (Females 13–50 years of age).	NOAEL = 4 mg/kg/day .... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.04 mg/kg/day ..... aPAD = 0.04 mg/kg/day	Developmental Studies in Rats. LOAEL = 5 mg/kg/day based on an increase of supernumerary ribs. The NOAEL is derived from a co-critical rat developmental study.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BROMOXYNIL FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary ..... (General population including infants and children).	NOAEL = 8 mg/kg/day .... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.08 mg/kg/day ..... aPAD = 0.08 mg/kg/day	Subchronic Study in Dogs. LOAEL = 12 mg/kg/day based on panting. In addition to panting, elevated rectal temperatures occurred at 16 mg/kg and above, and death occurred at 30 mg/kg and above after a single dose on day 1.
Chronic dietary ..... (All populations)	NOAEL= 1.5 mg/kg/day .. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.015 mg/kg/day ..... cPAD = 0.015 mg/kg/day	Chronic (1 year) Study in dogs. LOAEL = 7.5 mg/kg/day based on increased incidences of salivation, panting, liquid feces and pale gums; statistically significant decreased body weight gain over entire duration of study, but particularly during first 8 weeks of study; statistically significant decreased erythrocytes (RBC), hemoglobin (Hb) and packed cell volume (PCV); statistically significant increased urea nitrogen; increased absolute liver weights and liver/body weight ratios.
Cancer (Oral, dermal, inhalation).	Bromoxynil phenol has been classified by EPA as a Group C, possible human carcinogen, based on male mouse hepatocellular tumors. The Agency has determined that a linear low dose extrapolation model (Q_1*) should be applied to the experimental animal tumor data for quantification of human risk. Q_1* = 0.103 $(mg/kg/day)^{-1}$		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. Pad = population adjusted dose (a = acute, c = chronic), LOC = level of concern, RfD = Reference dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bromoxynil, EPA considered exposure under the petitioned-for tolerances as well as all existing bromoxynil tolerances in 40 CFR 180.324. EPA assessed dietary exposures from bromoxynil in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. Such effects were identified for bromoxynil. As shown in the table in this unit, EPA identified different PODs for assessing acute dietary exposure for the general population (including infants and children) and women of childbearing age (13 to 50 years).

In estimating acute dietary exposure, EPA used food consumption information from the U. S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residues in food, EPA assumed either tolerance level or anticipated residues. Tolerance levels were assumed for cotton, garlic, onion, peppermint, and spearmint. For all grains, average field trial values were used, since grains are considered to be blended commodities. Livestock anticipated residues were estimated using results from the crop field trials in conjunction with animal feeding studies. Additionally, maximum percent crop treated (PCT) estimates were used for all crop commodities. Default processing factors were used to estimate residues in processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used average field trial residues for all commodities except spearmint and peppermint, for which tolerance values were assumed. Livestock anticipated residues were estimated using average percent crop treated data, average field trial residue values, and results from the animal feeding studies. Additionally, average PCT estimates were used for all crop commodities. Default processing factors were used to estimate residues in processed commodities.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight-of-the-evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that bromoxynil should be classified as a "Possible Human Carcinogen," and a linear approach has been used to quantify cancer risk. Cancer risk was quantified using the same exposure estimates as discussed in Unit III.C.1.ii.—*chronic exposure.*

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the maximum PCT for existing uses in the acute dietary exposure assessment as follows: Alfalfa 2.5%; barley 35%; corn 5%; cotton 5%; flax 35%; garlic 70%; mint 25%; oats 5%; onion 70%; rye 1%; sorghum 2.5%; and wheat 35%.

The Agency estimated the average PCT for existing uses in the chronic and cancer dietary exposure assessments as follows: Alfalfa 1%; barley 20%; corn 2.5%; cotton 2.5%; flax 35%; garlic 50%; mint 25%; oats 5%; onion 55%; rye 1%; sorghum 2.5%; and wheat 15%.

The sorghum PCT values used in the acute and chronic assessments were based on existing uses. Because there is a proposed change in the sorghum use pattern (i.e., shorter pre-harvest interval), there is a potential for a change in the PCT value. However, grain sorghum is a small contributor to the overall livestock dietary burden estimate. If the PCT value for sorghum was assumed to be 100%, the overall impact to dietary exposure and risk assessment would be negligible.

In most cases, EPA uses available data from U. S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations are taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which bromoxynil may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for bromoxynil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of bromoxynil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of bromoxynil for acute exposures are estimated to be 11.5 parts per billion (ppb) for surface water and 3.26 parts per trillion (ppt) for ground water. EDWCs for chronic exposures for non-cancer assessments and cancer assessments are estimated to be 0.19 ppb for surface water and 3.26 ppt for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 11.5 ppb was used to assess the contribution to drinking water. For chronic and cancer dietary risk assessment, the water concentration value of 0.19 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Bromoxynil is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA 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."

EPA has not found bromoxynil to share a common mechanism of toxicity with any other substances, and bromoxynil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that bromoxynil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for bromoxynil includes five developmental toxicity studies in rats, two developmental toxicity studies in rabbits, a developmental study in mice, and 2- and 3-generation reproduction toxicity studies in rats. The available data indicate that bromoxynil produces developmental effects (supernumerary ribs) in rats and rabbits at or below the maternal NOAELs in both oral and dermal studies, and that bromoxynil octanoate produces supernumerary ribs at the maternal NOAEL in a dermal study. Supernumerary ribs were observed in rats, mice and rabbits after oral and/or dermal administration. Therefore, there is evidence of quantitative susceptibility in the database. However, clear NOAELs exist for the developmental effects, and basing the point of departure on these effects addresses Agency concerns for quantitative susceptibility.

In EPA's previous risk assessment for bromoxynil (1998), the FQPA SF was retained at 10X for the acute dietary endpoint for females, 13 to 50 years old, despite the POD being an adverse effect (supernumerary ribs) in the fetus. The primary reason for the retention was an apparent steepness of the dose-response curve (NOAEL = 4 mg/kg/day, LOAEL = 5 mg/kg/day) derived by combining the results of two co-critical studies. However, since the previous risk assessment for bromoxynil was conducted, a more refined data evaluation tool, benchmark dose (BMD) analysis, has become available and EPA has used it in this risk assessment to better characterize the dose-response relationship for supernumerary ribs. The analysis was conducted using the fetal and/or litter data available from the two rat developmental studies, plus a third developmental study which demonstrated similar results at similar dose levels. EPA also re-examined the underlying data for each study. EPA concluded that it was no longer appropriate to combine the rat developmental study with a NOAEL of 4 mg/kg/day with other studies in characterizing the dose-response relationship and that none of the studies indicate a steep dose-response curve. EPA further found that the results of the BMD analysis as to the study used to derive the POD (the rat developmental study with a NOAEL of 4 mg/kg/day) suggest a POD substantially higher than the NOAEL of 4 mg/kg/day, which supports the position that the NOAEL of 4 mg/kg/day is adequately protective of the adverse effect of supernumerary ribs in rat fetuses without an additional safety factor. Accordingly, EPA has determined, after re-examining all three studies, that the data on developmental effects do not raise any residual concerns.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for bromoxynil is complete, except for an immunotoxicity study (OPPTS Guideline 870.7800), and acute and subchronic neurotoxicity studies (OPPTS Guideline 870.6200a and 870.6200b), now required under 40 CFR 158.500 for pesticide registration. In the absence of specific immunotoxicity and acute and subchronic neurotoxicity studies, EPA has evaluated the available bromoxynil toxicity database to determine whether an additional database UF is needed to account for potential immunotoxicity or neurotoxicity.

With the exception of a marginal increase in the severity, but not the incidence, of thymic lymphocyte necrosis at otherwise toxic dose levels in a subchronic rat study, there is no evidence of immunotoxicity in the toxicology database for bromoxynil. Similarly, there is no evidence of neurotoxicity in the database. Consequently, EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under FQPA, and an additional database UF is not needed to account for the lack of these studies.

ii. Although there is evidence that bromoxynil results in increased quantitative susceptibility in *in utero* rats and rabbits in the prenatal developmental studies, EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of bromoxynil.

iii. There are no residual uncertainties identified in the exposure databases. Although the dietary assessments were refined, they were based on reliable and acceptable field trial and feeding studies and valid estimates of PCT. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to bromoxynil in drinking water. These assessments will not under estimate the exposure and risks posed by bromoxynil.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure to bromoxynil from food and water will occupy 7.4% of the aPAD for infants less than 1 year old, the population group receiving the greatest exposure. The acute dietary exposure to bromoxynil from food and water will occupy 4.4% of the aPAD for females 13 to 50 years old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to bromoxynil from food and water will utilize <1% of the cPAD for all population groups, including infants and children. There are no residential uses for bromoxynil.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure take into account short- or intermediate-term residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, bromoxynil is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risks are assessed based on short- or intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- and intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for bromoxynil.

4. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in this unit for the cancer risk assessment, EPA has concluded that exposure to bromoxynil from food and water will result in a lifetime cancer risk of 1.5×10^{-6} for the

general U.S. population. EPA generally considers cancer risks in the range of one in one million (1×10^{-6}) or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. Although the bromoxynil exposure risk assessment is refined, it retains some conservatism due, among other things, to the use of field trial data and screening level PCT information to estimate residues in food. Accordingly, EPA has concluded the cancer risk for all existing bromoxynil uses and the uses associated with the tolerances established in this action falls within the range of 1×10^{-6} and is thus negligible.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to bromoxynil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression for residues of bromoxynil in grass and grain sorghum commodities. Method I in the *Pesticide Analytical Manual* (PAM), Vol. II, is a gas liquid chromatography/microcoulometric detection (GLC/MCD) method that has undergone a successful EPA method validation on wheat grain. Method Ia is the same method except that it uses gas chromatography/electron capture detection (GC/ECD) for determination of methylated bromoxynil.

Adequate residue analytical methodology is available for tolerance enforcement for bromoxynil in livestock commodities. Method A is a GC/MCD or GC/ECD method for the analysis of bromoxynil residues in livestock tissues and is essentially the same as Method I. Method B is a GC/ECD method that is also similar to Method I, with modifications to the cleanup procedures. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for bromoxynil on the commodities in this rule.

C. Revisions to Petitioned-For Tolerances

The proposed increases in the tolerance levels for "grass, forage;" "grass, hay;" and "sorghum, grain" were determined to be appropriate for these commodities. However, EPA determined that the existing tolerance for "sorghum, grain, forage" must also be increased from 0.5 ppm to 0.8 ppm, based on analysis of the field trial data using the Agency's tolerance/MRL calculator in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data.* In addition, because the tolerance on the grain of grain sorghum is being increased from 0.05 ppm to 0.2 ppm, higher residues may occur in aspirated grain fractions; and EPA has determined that the existing tolerance should be increased from 0.3 ppm to 1.2 ppm. Finally, based on calculated livestock dietary burdens in light of the new tolerances and data from a cattle feeding study, EPA has determined that the established tolerance for milk must be increased from 0.1 ppm to 0.4 ppm.

EPA is also revising the tolerance expression for existing tolerances and the new tolerances to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be determined. Tolerances for most plant commodities are currently expressed in terms of "bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) resulting from application of its octanoic and/or heptanoic acid ester." Livestock tolerances and tolerances for cotton commodities are currently expressed in terms of "bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) and its metabolite 3,5-dibromo-4-hydroxybenzoic acid (DBHA) resulting from application of its octanoic and/or heptanoic acid ester." The tolerance expression for plants, except cotton, is being revised to make clear that the tolerances cover residues of bromoxynil, including its metabolites and degradates, but that compliance with the tolerances is to be determined by measuring only bromoxynil. Similarly, the tolerance expression for livestock commodities and cotton is being revised to clarify that the tolerances cover residues of bromoxynil, including its metabolites and degradates, but that compliance with the tolerance levels will be determined by measuring only bromoxynil and its metabolite DBHA. EPA has determined that it is reasonable to make these changes final without prior proposal and opportunity for comment, because public comment is not necessary, in that the changes have no substantive effect on the tolerances, but rather are merely intended to clarify the existing tolerance expressions.

V. Conclusion

Therefore, previously established tolerances are amended for residues of bromoxynil, including its metabolites and degradates, as set forth in the regulatory text.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,*

nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled C*onsultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995, Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: May 18, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.324 is amended as follows:

■ i. Revise the introductory text in paragraph (a)(1), and the entries for grain, aspirated fractions; grass, forage; grass, hay; sorghum, grain, forage; and sorghum, grain, grain in the table to paragraph (a)(1).

■ ii. Revise the introductory text in paragraph (a)(2), and the entry for "milk" in the table to paragraph (a)(2).

The revisions read as follows:

§ 180.324 Bromoxynil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide bromoxynil, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only bromoxynil, 3,5-dibromo-4-hydroxybenzonitrile, resulting from application of its octanoic and/or heptanoic acid ester, in or on the commodities.

Commodity	Parts per million
* * * * *	
Grain, aspirated fractions	1.2
Grass, forage	18
Grass, hay	5.0
* * * * *	
Sorghum, grain, forage	0.8
Sorghum, grain, grain	0.2
* * * * *	

(2) Tolerances are established for residues of the herbicide bromoxynil, 3,5-dibromo-4-hydroxybenzonitrile, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only bromoxynil and its metabolite, 3,5-dibromo-4-hydroxybenzoic acid (DBHA), resulting from application of its octanoic and/or heptanoic acid ester, in or on the commodities.

Commodity	Parts per million
* * * * *	
Milk	0.4
* * * * *	

* * * * *

[FR Doc. 2011–13565 Filed 5–31–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 110502274–1275–01]

RIN 0648–BB05

Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Closure of the Nantucket Lightship Access Area

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

ACTION: Temporary rule; emergency action.

SUMMARY: NMFS issues this temporary rule pursuant to its authority to implement emergency measures under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). This emergency rule closes the Nantucket Lightship Access Area (NLS) prior to its scheduled opening on June 15, 2011, and is consistent with Framework Adjustment 22 to the Atlantic Sea Scallop Fishery Management Plan (FMP) (Framework 22), which is currently being proposed and subject to public comments, and which would close the NLS in FY 2011 as well. This closure prevents potentially high levels of scallop and yellowtail flounder (yellowtail) catch that could result from opening the area prior to the approval and implementation of Framework 22, which could be detrimental to the long-term management and health of the scallop fishery.