on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Act. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The Congressional Review Act, 5 U.S.C. section 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. section 804(2).

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 13, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 3, 2001.

Laura Yoshii,

Acting Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52 [AMENDED]

1. The authority citation for Part 52 continues to read as follows:

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

Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c)(173)(i)(F) and (c)(282) to read as follows:

§ 52.220 Identification of plan.

(c) * * *

(173) * * *

(i) * * *

(F) South Coast Air Quality Management District.

(*1*) Rule 443.1, adopted on December 5, 1986.

* * * * *

(282) New and amended regulations for the following APCDs were submitted on May 31, 2001, by the Governor's designee.

(i) Incorporation by reference.

(A) Bay Area Air Quality Management District.

(*1*) Rule 8–51, adopted on May 2, 2001.

* * * * *

[FR Doc. 01–22736 Filed 9–11–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301163; FRL–6798–2]

RIN 2070–AB70

Bromoxynil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of bromoxynil in or on timothy, hay and timothy, forage. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on timothy. This regulation establishes a maximum permissible level for residues of bromoxynil in these commodities. These tolerances will expire and are revoked on June 30, 2003.

DATES: This regulation is effective September 12, 2001. Objections and requests for hearings, identified by docket control number OPP–301163, must be received by EPA on or before November 13, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301163 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6463; and e-mail address: madden.barbara@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 categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301163. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the insecticide bromoxynil, 3,5-dibromo-4-hydroxybenzonitrile, in or on timothy, hay at 0.50 part per million (ppm) and timothy, forage at 0.10 ppm. These tolerances will expire and are revoked on June 30, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to 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) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Bromoxynil on Timothy and FFDCA Tolerances

On May 4, 2001, the Nevada Department of Agriculture availed themselves of the authority to declare a crisis exemption for use of bromoxynil in fields planted with both timothy and alfalfa to control weeds. Very recent overplanting of aging alfalfa fields with timothy revealed a problem with weed control in that no registered herbicides are available for use on alfalfa and timothy that do not damage the other crop. Bromoxynil, which is registered for use on alfalfa, does not damage timothy. The crisis declaration was made because alfalfa growth had reached a point where applications would be ineffective if done any later in the season. EPA has authorized under FIFRA section 18 the use of bromoxynil on timothy for control of weeds in Nevada.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of bromoxynil in or on timothy, hay and timothy, forage. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on June 30, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on timothy, hay and timothy, forage after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance

earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether bromoxynil meets EPA's registration requirements for use on timothy or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of bromoxynil by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Nevada to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for bromoxynil, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D), 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 bromoxynil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of bromoxynil in or on timothy, hay at 0.50 ppm and timothy, forage at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for bromoxynil used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BROMOXYNIL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for RiskAssessment	Study and Toxicological Effects
Acute Dietary females 13–50 years of age	NOAEL = 4 mg/kg/day UF = 100 Acute RfD = 0.04 mg/kg/day	FQPA SF = 10 aPAD = acute RfD ÷ FQPA SF = 0.004 mg/kg/day	Developmental toxicity study where bromoxynil phenol was administered to rats. LOAEL = 5 mg/kg/day based on an increased incidence of supernumerary ribs in rats from a developmental toxicity study.
Acute Dietary general population including infants and children	NOAEL = 8 mg/kg/day UF =100 Acute RfD = 0.08 mg/kg/day	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.08 mg/kg/day	13–Week range-finding study in which bromoxynil phenol was administered orally to dogs. LOAEL = 12 mg/kg/day based on increased incidence of panting on day 1, suggestive of a compensatory reaction to the effects of the test material, which at higher doses is expressed as elevated body temperature.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BROMOXYNIL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for RiskAssessment	Study and Toxicological Effects
Chronic Dietary all populations	NOAEL= 1.5 mg/kg/day UF = 100 Chronic RfD = 0.015 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.015 mg/kg/day	12–Month chronic oral toxicity study in dogs using bromoxynil phenol as the test material. Threshold NOAEL/LOAEL of 1.5 mg/kg/day based on slightly decreased body weight gain in males. At the next higher dose level (7.5 mg/kg/day), the following effects were observed in both males and females: decreased body weight gain; increased salivation, panting, liquid feces, and pale gums; decreased erythrocytes, hemoglobin, and packed cell volume; increased urea nitrogen; and increased liver weights.
Cancer (oral, dermal, inhalation)	Bromoxynil phenol has been classified as a Group C, possible human carcinogen. A low dose extrapolation model (Q1*) is applied for quantification of human risk. Q1* = 1.03 x 10^{-1} $(mg/kg/day)^{-1}$	10^{-6}	The weight-of-the-evidence determination was based primarily on results in two mouse carcinogenicity studies.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.324) for the residues of bromoxynil, in or on a variety of raw agricultural commodities including alfalfa, barley, corn, flax, garlic, mint, oats, onions, rye, sorghum, wheat, and cotton. Tolerances have also been established on fat, meat, and meat-by-products of cattle, goats, hogs, horses, poultry, and sheep as well as eggs and milk. Risk assessments were conducted by EPA to assess dietary exposures from bromoxynil in food as follows.

Bromoxynil is currently registered for use on alfalfa. The aggregate risks associated with the use of bromoxynil on alfalfa have been assessed previously (Reregistration Eligibility Decision (RED) document, Decmeber 1998). No residue data are available for bromoxynil on timothy. As the use directions for timothy-alfalfa stands are the same as for alfalfa alone, the state has proposed to translate the existing residue data for alfalfa (a member of Crop Group 18, Nongrass Animal Feeds) to timothy (a member of Crop Group 17; Grass Forage, Fodder and Hay). This translation would generally not be possible as the timothy, forage tolerance would be based on 0–day preharvest interval (PHI) data whereas the PHI for alfalfa, forage is 30 days. However, as the cultural practices for timothy-alfalfa stands is the same as that for alfalfa alone, for the emergency exemption only, the Agency is willing to translate the existing alfalfa residue data to timothy. Based upon the alfalfa residue data, the following tolerances are thus appropriate for timothy, hay at 0.50 ppm and timothy, forage at 0.10 ppm.

There are no human food items associated with timothy and therefore, the use of bromoxynil on timothy will not increase the potential for secondary residues in livestock (since the residues in timothy will not exceed those on alfalfa, a more significant feed item), the dietary risk associated with bromoxynil will not be effected by this use. The potential for residues in drinking water will not be effected as the use rate for timothy-alfalfa stands is the same as for alfalfa alone. Thus, revised risk assessments were not conducted for this action. The information discussed below was previously discussed in the December 1998 RED document.

i. *Acute exposure.* Acute dietary 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. In 1998, an acute (probabilistic) dietary analysis including the cotton use was performed by Novigen Sciences, Inc. for Rhone Poulenc. The assessment used the consumption data from the USDA 1989–1992 nationwide Continuing Survey of Food Intakes by Individuals (CSFII).

The acute dietary risk assessment was conducted as a probabilistic risk assessment, assuming single day exposure. In the assessment, each person-day of food consumption was matched with randomly selected residue values for this assessment from field trails submitted in support of the chemical. Percent crop treated data were included in the assessment as zeroes to account for portions of the crop to which bromoxynil was not applied. This process was repeated one thousand times for each person-day in consumption data base. The assessment assumed that the treated commodities were evenly distributed in the food supply. Secondary residues in meat and milk from consumption of treated feed items were included in the form of a probabilistic assessment, varying residues in the diet in accordance with the data from the field trials. The assumptions for the dietary exposure were reviewed and found to be acceptable. The assessments assumed that 10% of the cotton crop would be treated.

Anticipated residues in blended commodities (such as grains, cottonseed and mint oil) were used, without an adjustment for percent crop treated; however, tolerance level residues were used for onions, garlic, fat, meat by-products, and meat of cattle, goats, hogs, horses, sheep, and poultry, and eggs. Milk is a blended commodity, and therefore an anticipated residue was used.

ii. *Chronic/cancer exposure.* In conducting this chronic dietary risk

assessment the Dietary Risk Evaluation System (DRES) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Field trial residues in raw agricultural commodities (RACs) consumed by people were nondetectable; anticipated residues were based on ½ the limit of quantitation (LOQ), and were further refined by percent crop treated data. Field trial residues from all forages (i.e., sorghum, wheat, oat, corn, alfalfa), and all hays were averaged, and the additional refinement for percent crop treated was applied. Although forages and hays contained detectable bromoxynil residues, the averages used were significantly lower than tolerance-level residues.

The contribution of cotton gin products (gin trash) to the dietary burden for ruminants was assumed to be 5% of the diet for beef cattle and 1% for dairy cattle. It was assumed that 10% of cotton was treated. The only commodities which contribute significantly to exposure to bromoxynil and/or DBHA in the diet for the general U.S. population (or any subpopulation) are meat, milk, poultry, and eggs, based on secondary residues resulting from consumption of livestock feed items.

iii. *Anticipated residue and percent crop treated information*. Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

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

• Condition 1, that 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 such pesticide residue.

• Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition 3, if 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 section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: 10% of the cereal grains (wheat, corn, oats, barley, rye, sorghum, including processed commodities) treated; 62% of onions treated; 100% garlic treated; 71% of the peppermint and spearmint treated, and 10% of the cotton treated. Refer to the December 1998 RED docucment for additional information.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is 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 information on the regional consumption of food to which bromoxynil may be applied in a particular area.

2. *Dietary exposure from drinking water*—i. *Ground water*. Bromoxynil octanoate does not exhibit the mobility or persistence characteristics of pesticides that are normally found in ground water. Bromoxynil phenol (which bromoxynil octanoate readily degrades to) has the potential to leach to ground water under certain conditions; however, it rapidly degrades under aerobic and anaerobic conditions reducing the likelihood of ground water contamination. Limited monitoring information for bromoxynil in ground water is available. The ''Pesticides in Ground Water Database'' (EPA 1992) reports sampling for bromoxynil in 107 wells in four counties in Oregon between 1985 and 1987. The well samples in each area (public water supply and domestic) were selected based on suspected vulnerability, susceptibility to contamination, and availability of information on well construction and depth. No additional information on the details of the monitoring was available. No detections of bromoxynil were reported.

Additional monitoring data from the United States Geological Survey (USGS) National Water Quality Program (NAQWA) represent the highest quality data and most recent data available (1993–1994). The program was carefully designed to obtain monitoring data for surface and ground waters from diffuse (non-point) sources. For ground water, one detection of bromoxynil (concentration not specified) was reported from a total of 2,245 samples. Clearly, these compounds (bromoxynil phenol and octanoate) are not considered candidates for restricted use due to ground water concerns and the potential for ground water contamination (and exposure) from bromoxynil is extremely low.

DBHA, a cotton metabolite, is not expected to be found in ground water.

ii. *Surface water*. Environmental fate studies indicate that bromoxynil (phenol and octanoate) should not persist in surface waters, although water monitoring data from the USGS NAWQA program show that bromoxynil has been detected in 1.1% of surface water samples. Modeled estimated environmental concentrations (EECs)

were based on the cotton use and not the small grains, corn or other uses of bromoxynil because, it has been the Agency's experience, that using cotton as opposed to these crops results in a higher estimated surface water exposure. Cotton represents the most conservative use for surface water exposure (i.e., the highest possible exposure scenario).

A Tier II analysis based on the PRZM-EXAMS model (Pesticide Root Zone Model Version 2.3 plus Exposure Analysis Modeling System Version 2.94) was conducted for the cotton use. PRZM-EXAMS uses data on the physical-chemical properties of the pesticide plus soil and topographic characteristics, weather data, and water quality parameters for the modeled site. The model uses this information to estimate runoff from a 10 hectare agricultural field into an immediately adjacent 1 hectare by 2 meter deep pond. PRZM-EXAMS considers reduction in dissolved pesticide concentrations 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.

Water monitoring data from the USGS NAWQA Program were reported during the 1993–1995 period from 7 of 20 river basins throughout the U.S. The NAWQA Program examined drainage basins that were primarily agricultural use. The percentage of detections was 1.1% from a total of 1,925 surface water samples. Analysis of the 20 detections >0.03 parts per billion (ppb) yielded a median value of 0.105 ppb with a mean of 0.53 ppb. The maximum concentration was one data point at 6.1 ppb (12.2 ppb when accounting for 50% recovery) measured in the South Platte River Study Unit, CO. For urban land use, bromoxynil was not detected in surface waters. It is important to note the laboratory recoveries were approximately 50%. Apparently the laboratory recoveries did not vary considerably from the 50% level.

Based on model estimates (using PRZM-EXAMS), the maximum or peak estimated concentration for bromoxynil was 12.3 ppb and the maximum estimated long-term mean was 0.24 ppb (using 36 years of weather data). These values represent what might be expected in a small water body near a cotton field highly prone to runoff. The maximum peak estimated concentration for bromoxynil from the model correlates with the highest value detected in the USGS monitoring data, when this measured value has been corrected for an analytical recovery rate of 50%.

To estimate a reasonable high end exposure for the human health risk assessment, EPA focused on the calculated time-weighted annual mean concentrations of bromoxynil at each of 11 USGS monitoring sites, which the EPA views as located in watersheds likely to have bromoxynil use. (These values were not corrected for the analytical recovery rate of 50%.) These time-weighted annual mean concentrations ranged from 0.011 ppb to 0.18 ppb, with 10 out of the 11 sites with time-weighted annual mean concentrations below 0.05 ppb. Six of the 10 sites had time weighted annual mean concentrations at or below 0.014 ppb. The highest annual time-weighted mean (0.18 ppb) was located in a relatively small watershed (approximately 100 square miles) in a relatively small water body, and the calculated annual mean value at this site was significantly influenced by the presence of a single high value (the highest value found in all of the available monitoring data). Based on this information, EPA believes that 0.05 ppb is a reasonable high end estimate for purposes of estimating drinking water exposure.

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 use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a 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.''

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 based on a common mechanism of toxicity, 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. 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure 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 (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

The bromoxynil data submitted to the Agency for review are sufficient for the assessment of hazard to the developing organism. A total of 11 developmental and 3 reproductive toxicity studies were available for review. These include oral prenatal developmental toxicity studies (three in rats, two in rabbits, and one in mice with the phenol; one in rats with the octanoate), dermal prenatal developmental toxicity studies (one each in rats and rabbits with both the phenol and the octanoate), and two dietary two-generation reproduction studies in rats (one with the phenol; one with the octanoate) and one dermal reproduction study. Developmental toxicity was observed, following *in utero* exposure to bromoxynil, in multiple studies, by two routes of exposure, and in three species. The induction of supernumerary ribs was shown to be the most sensitive indicator of developmental toxicity in fetal rats, mice, and (in certain studies) rabbits. Upon consideration of the data base in its entirety, the Agency determined that the developmental NOAEL, for the induction of supernumerary ribs, resulting from prenatal exposure to bromoxynil (phenol) is 4 mg/kg/day via the oral route and 10 mg/kg/day via the dermal route. The developmental LOAELs for bromoxynil phenol were 5 mg/kg/day by the oral route and 50 mg/kg/day by the dermal route. Other forms of developmental toxicity, including resorptions and malformations, were routinely observed in bromoxynil studies at higher dose levels.

It was determined that the FQPA safety factor should be retained for the subpopulation consisting of females 13+ for acute dietary exposures. This

decision was based upon concerns emanating from the toxicological profile, including evidence of increased susceptibility of fetuses to bromoxynil exposure, the steep dose response curve, and the demonstrated severe developmental effects at doses above the LOAEL.

The population of concern is the developing fetus and the endpoint of concern is supernumerary ribs. This endpoint, a developmental anomaly, results from *in utero* exposure; therefore the population subgroup of concern is females 13+ years old. Although some systems in infants and children continue developing, it is unlikely that supernumerary ribs, even though observed across multiple species, would result from postnatal exposure. A 10–fold safety factor, as required by FQPA, will provide additional protection for infants and children and ensure a reasonable certainty of no harm to this sensitive subpopulation.

D. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure and dietary exposure from drinking water, the acute aggregate exposure from food and water to bromoxynil will occupy <1% of the aPAD for the U.S. population, 11% of the aPAD for females 13 years and older, 2% of the aPAD for all infants and 2% of the aPAD for children 1–6 years old. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO BROMOXYNIL

Population Subgroup	aPAD (mg/kg)	Estimated Exposure from Food (mg/kg bw/day)	Estimated Exposure from Water (mg/kg/day)	% aPAD (Food and Water)
U.S. population	0.08	0.000137	0.00035	<1%
Females 13+ years	0.004	0.000082	0.00035	11%
Children (1–6 years old)	0.08	0.000288	0.0012	2%
All infants	0.08	0.000219	0.0012	2%

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure and dietary exposure from drinking water, EPA has concluded that exposure to bromoxynil from food and water will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants, and <1% of the cPAD for children 1–6 years old. There are no residential uses for bromoxynil that result in chronic residential exposure to bromoxynil. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BROMOXYNIL

Population Subgroup	cPAD (mg/kg)	Estimated Exposure from Food (mg/kg bw/day)	Estimated Exposure from Water (mg/kg/day)	% cPAD (Food and Water)
U.S. population	0.015	0.000015	0.0000014	<1%
Females 13+ years	0.015	0.000012	0.0000016	<1%
Children (1–6 years old)	0.015	0.000032	0.000005	<1%
All Infants	0.015	0.000036	0.000005	<1%

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Bromoxynil is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Bromoxynil is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population*. Using the exposure assumptions described in this unit for chronic/cancer exposure and dietary exposure from drinking water, EPA has concluded that exposure to bromoxynil from food and water resulted in an estimated aggregate cancer risk to the U.S. population of 1.7×10^{-6}. Bromoxynil is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate cancer risk is the sum of the risk from food and water only.

6. *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, and to infants and children from aggregate exposure to bromoxynil residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methodology is available for data collection and tolerance enforcement for bromoxynil per se in plants. Method I in PAM, Vol. II, is a GLC/MCD that has undergone a successful EPA method validation on

wheat grain. This method involves alkaline hydrolysis in methanolic KOH to convert residues to bromoxynil, cleanup by liquid-liquid partitioning, methylation using diazomethane, further cleanup on a Florisil column, and determination by GLC/MCD. Method Ia is the same method, but uses GC/ECD for determination of methylated bromoxynil.

Method A is a GC/MCD or 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.

B. International Residue Limits

There are no established or proposed Codex maximum residue levels for bromoxynil residues; no compatibility questions exist with respect to U.S. tolerances and Codex.

VI. Conclusion

Therefore, the tolerance is established for residues of bromoxynil, 3,5-dibromo-4-hydroxybenzonitrile, in or on timothy, hay at 0.50 ppm and timothy, forage at 0.10 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301163 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 13, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301163, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. 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). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates

Reform Act of 1995 (UMRA) (Public Law 104–4). 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); or OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

Because this rule has been exempted from review under Executive Order 11866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001).

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this 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: August 28, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.324 is amended by adding text to paragraph (b) to read as follows:

§ 180.324 Bromoxynil, tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions*. Time-limited tolerances are established for residues of the insecticide bromoxynil, 3,5-dibromo-4-hydroxybenzonitrile in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Timothy, hay	0.50 ppm	6/30/03
Timothy, forage	0.10 ppm	6/30/03

* * * * *

[FR Doc. 01–22526 Filed 9–11–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301161; FRL–6797–5]

RIN 2070–AB78

Fludioxonil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile) in or on pomegranates. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on pomegranates. This regulation establishes a maximum permissible level for residues of fludioxonil in this food commodity. The tolerance will expire and is revoked on June 30, 2003.

DATES: This regulation is effective September 12, 2001. Objections and requests for hearings, identified by docket control number OPP–301161, must be received by EPA on or before November 13, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301161 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9367; and e-mail address: ertman.andrew@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 categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2.*In person*. The Agency has established an official record for this action under docket control number OPP–301161. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the fungicide fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile), in or on pomegranates at 5.0 parts per million (ppm). This tolerance will expire and is revoked on June 30, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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