§ 180.910 Inert ingredients used pre-harvest and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	*	*
Potassium benzoate (as No. 582–25–2).	none	preservative
* * *	*	*

■ 3. In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	*	*
Potassium benzoate (as No. 582–25–2).	none	preservative
* * *	*	*

[FR Doc. 2011–5051 Filed 3–8–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0122; FRL–8858–5]

Fomesafen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fomesafen in or on pepper (bell and non-bell), potato, and tomato. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 9, 2011. Objections and requests for hearings must be received on or before May 9, 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–2010–0122. 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.*

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–2010–0122 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 May 9, 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–2010–0122, 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 Registers** of September 4, 2009 (74 FR 45848) (FRL–8434–4) and March 19, 2010 (75 FR 13277) (FRL–8813–2), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 9F7563 and PP 9F7667) by Syngenta Crop Protection, Inc., PO Box 18300, Greensboro, NC 27419–8300. The petitions requested that 40 CFR 180.433

be amended by establishing tolerances for residues of the herbicide fomesafen, 5-[2-cloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide, in or on potato and tomato (PP 9F7563); and pepper (PP 9F7667) at 0.025 parts per million (ppm). Those notices referenced summaries of the petitions prepared by Syngenta Crop Protection, Inc., the registrant, which are available in the dockets, *http://www.regulations.gov.* There were no comments received in response to the notice of filing of PP 9F7563. Comments were received on the notice of filing of PP 9F7667. EPA's response to these comments is discussed in Unit IV.C.

EPA has revised the proposed tolerance expression and the commodity terms for peppers in accordance with current Agency policy. These revisions are discussed in Unit IV.D.

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 fomesafen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fomesafen 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.

Fomesafen has a low order of acute toxicity by the oral route of exposure, is severely irritating to the eye, and is moderately irritating to the skin. In the subchronic and chronic toxicity studies in rats and mice, food consumption or food efficiency, body weight/body weight gain, and histopathological changes in the liver were the parameters that were most often affected. Dogs and mice also showed hematological changes (*e.g.,* decreased erythrocyte count, hemoglobin, or hematocrit). There was no evidence of neurotoxicity or immunotoxicity in the toxicological studies with fomesafen. There was no evidence that fomesafen results in increased susceptibility of rat or rabbit fetuses in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

There was no evidence of carcinogenicity in the rat chronic toxicity/carcinogenicity study. Liver tumors were produced in the mouse carcinogenicity study; however, EPA classified fomesafen as "Not Likely to be Carcinogenic to Humans," based on the weight-of-evidence supporting activation of peroxisome proliferator-activated receptor alpha (PPARα) as the mode of action for fomesafen-induced hepatocarcinogenesis in mice. The data did not support either mutagenesis or cytotoxicity followed by regenerative proliferation as alternative modes of action. While the proposed mode of action for liver tumors in mice is theoretically plausible in humans, it is unlikely to take place in humans based on quantitative species differences in PPARα activation and toxicokinetics. Detailed information on the factors EPA considered in making this determination can be found at *http://www.regulations.gov* in the document "FOMESAFEN: Second Report of the Cancer Assessment Review Committee" in docket ID number EPA–HQ–OPP–2010–0122.

Specific information on the studies received and the nature of the adverse effects caused by fomesafen 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 the document "Fomesafen Sodium: Human Health Risk Assessment for the Establishment of Tolerances and Registration of New Uses of Fomesafen Sodium on Potatoes and Peppers," p. 30 in docket ID number EPA–HQ–OPP–2010–0122.

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 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 no adverse effects are observed (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) 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 fomesafen used for human risk assessment is shown the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FOMESAFEN 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 (All population subgroups, including Females 13–49 years of age, infants and children).	No toxic effects attributable to a single dose of fomesafen were found in the database.		
Chronic dietary (All populations)	NOAEL= 0.25 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0025 mg/kg/day cPAD = 0.0025 mg/kg/day.	Chronic toxicity—rat LOAEL = 5 mg/kg/day based on hyalinization of the liver in males.
Cancer (Oral, dermal, inhalation) ..	Fomesafen is classified as "Not Likely to be Carcinogenic to Humans."		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fomesafen, EPA considered exposure under the petitioned-for tolerances as well as all existing fomesafen tolerances in 40 CFR 180.433. EPA assessed dietary exposures from fomesafen 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. No such effects were identified in the toxicological studies for fomesafen; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that residues would be present in all commodities at the tolerance level and that 100% of all crops are treated with fomesafen. Dietary Exposure Evaluation Model/Food Commodity Intake Database (DEEM–FCID™), Version 2.03, default processing factors were used to determine residues in processed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fomesafen does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for fomesafen. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used a screening-level water exposure model to estimate residues of fomesafen in surface water. This simulation model, the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), takes into account data on the physical, chemical, and fate/transport characteristics of fomesafen. 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 model results, the estimated drinking water concentration (EDWC) of fomesafen for chronic exposures for non-cancer assessments is estimated to be 10.535 parts per billion (ppb) for surface water.

The Agency estimated residues of fomesafen in ground water based on the results of a prospective ground water monitoring study, submitted by the registrant, Syngenta Crop Protection, Inc. The maximum residue found in the study, which was conducted on a vulnerable North Carolina soil using a soybean cropping system, was 1 ppb, an order of magnitude lower than the modeled estimate for surface water.

The modeled estimate of fomesafen in surface water was used in the dietary exposure analysis and risk assessment for fomesafen in drinking water. For chronic dietary risk assessment, the water concentration of value 10.535 ppb was directly entered into the dietary exposure model 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). Fomesafen 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."

Fomesafen is a member of the diphenyl ether chemical family. The common toxicity that these compounds share is induction of liver effects (liver hypertrophy, increase in liver weight, tumors). Members of this class have been shown to induce rodent liver effects/tumors through the activation of the peroxisome proliferator-activated receptor (PPARα). It should be noted that liver hypertrophy and increases in liver weight are part of the range of morphological changes that result from chemically-mediated effects on the PPARα receptor and hepatocarcinogenesis. Although PPARα agonists can induce liver rodent tumors, the potential for PPARα agonists to induce liver tumors in other species, including humans, appears to be unlikely. This is because evidence shows that these other species are quantitatively less sensitive to the effects of PPARα agonism due to toxicodynamic differences between the human and rodent nuclear PPARα receptor. Thus, while this mode of action for liver tumors in rodent is

qualitatively possible in humans, it is unlikely to take place in humans based on quantitative species differences in PPARα activation and toxicokinetics. Accordingly, although members of the diphenyl ether family, as well as other classes of compounds, may share a common hepatocarcinogenic mode of action, cumulative exposure to PPARα agonists is unlikely to induce liver carcinogenesis in humans.

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 Safety Factor (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 pre- and postnatal database for fomesafen includes a prenatal developmental toxicity study in rabbits, two prenatal developmental toxicity studies in rats, and a 2-generation reproduction toxicity study in rats. The rabbit developmental study was classified as unacceptable because of bacterial infection in the colony; however, the study provided information to assess potential developmental toxicity in rabbits. There was no significant difference between the treated and control animals for developmental abnormalities in the rabbit study. In the two rat developmental studies (considered together), developmental effects (postimplantation loss) occurred at the same dose causing maternal toxicity (staining of the ventral fur and significantly decreased body weight gain (>10%)). In the rat reproduction study, offspring effects (increased incidence of liver hyalinization in males) occurred at the same dose causing parental effects (liver histopathology in males and females of both generations).

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 fomesafen is largely complete, lacking only immunotoxicity and acute and subchronic neurotoxicity studies. EPA has evaluated the available toxicity data for fomesafen and determined that an additional database uncertainty factor is not needed to account for the lack of these studies. As stated in Unit III.A, fomesafen primarily impacts the parameters of food consumption or food efficiency, body weight/body weight gain, and histopathological changes in the liver. There is no evidence that fomesafen causes immunotoxic or neurotoxic effects in any of the available toxicity studies, and EPA does not believe that conducting immunotoxicity and acute/subchronic neurotoxicity testing will result in a NOAEL less than 0.25 mg/kg/day, which is presently used as the point of departure for chronic risk assessment.

ii. There is no indication that fomesafen is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fomesafen results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the surface water modeling used to assess exposure to fomesafen in drinking water. These assessments will not underestimate the exposure and risks posed by fomesafen.

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 acute PAD (aPAD) and chronic PAD (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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fomesafen is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fomesafen from food and water will utilize 32% of the cPAD for infants, less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for fomesafen.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- or intermediate-term residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Short-/intermediate-term adverse effects (hyalinization of hepatocytes, increased eosinophilia, reduced granulation, increased liver weights in males and females, and increases in plasma alkaline phosphatase, alanine transminase and aspartate transaminase in males in the 90-day rat feeding study) were identified; however, fomesafen 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-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 fomesafen.

4. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A, EPA has concluded that the mode of action for fomesafen-induced hepatocarcinogenesis in mice is unlikely to take place in humans; therefore, fomesafen is not expected to pose a cancer risk to humans.

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 fomesafen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography with tandem mass spectrometry detection (HPLC/MS/MS)) is available to enforce the tolerance expression. The method 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 fomesafen on pepper, potato, or tomato.

C. Response to Comments

An anonymous citizen objected to the presence of any pesticide residues on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-for Tolerances

In its petition PP 9F7667, the registrant proposed a tolerance of 0.025 ppm for residues of fomesafen in or on the commodity "pepper." Consistent with recommendations in the Agency's Food and Feed Commodity Vocabulary, EPA is establishing separate tolerances for "pepper, bell" and "pepper, non-bell" at 0.025 ppm each.

EPA is also revising the requested tolerance expression to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expression makes clear that the tolerances cover residues of the herbicide fomesafen, including its metabolites and degradates, but that compliance with the tolerance levels is to be determined by measuring only fomesafen, 5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide.

V. Conclusion

Therefore, tolerances are established for residues of fomesafen, including its metabolites and degradates, in or on pepper, bell; pepper, non-bell; potato; and tomato at 0.025 ppm. Compliance with the tolerance levels is to be determined by measuring only fomesafen, 5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide.

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 (PRA), 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 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.

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 *Consultation 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 (UMRA) (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 (NTTAA), 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: February 28, 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 180.433 is amended by revising the introductory text in paragraph (a) and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.433 Fomesafen; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide fomesafen, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels specified in the following table below is to be determined by measuring only fomesafen, 5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide, in or on the commodity.

Commodity	Parts per million
* * * *	
Pepper, bell	0.025
Pepper, non-bell	0.025
Potato	0.025
* * * *	
Tomato	0.025

* * * * *

[FR Doc. 2011–5070 Filed 3–8–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 040205043–4043–01]

RIN 0648–XA229

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery of the South Atlantic; Closure

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the commercial sector for golden tilefish in the exclusive economic zone (EEZ) of the South Atlantic. This closure is necessary to protect the golden tilefish resource.

DATES: This rule is effective 12:01 a.m., local time, March 9, 2011, until 12:01 a.m., local time, January 1, 2012.

FOR FURTHER INFORMATION CONTACT: Catherine Bruger, telephone: 727–824–5305, fax: 727–824–5308, e-mail: *Catherine.Bruger@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act by regulations at 50 CFR part 622.

The commercial quota for golden tilefish in the South Atlantic is 282,819 lb (128,284 kg) for the current fishing year, January 1 through December 31, 2011, as specified in 50 CFR 622.42(e)(2).

Under 50 CFR 622.43(a), NMFS is required to close the commercial sector for golden tilefish when its quota has been reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that the commercial quota for South Atlantic golden tilefish will have been reached by March 9, 2011. Accordingly, the commercial sector for South Atlantic golden tilefish is closed effective 12:01 a.m., local time, March 9, 2011, until 12:01 a.m., local time, January 1, 2012.

The operator of a vessel with a valid commercial vessel permit for South Atlantic snapper-grouper having golden tilefish onboard must have landed and bartered, traded, or sold such golden tilefish prior to 12:01 a.m., local time, March 9, 2011. During the closure, the bag limit and possession limits specified in 50 CFR 622.39(d)(1)(ii) and (d)(2), respectively, apply to all harvest or possession of golden tilefish in or from the South Atlantic EEZ, and the sale or purchase of golden tilefish taken from the EEZ is prohibited. The prohibition on sale or purchase does not apply to the sale or purchase of golden tilefish that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, March 9, 2011, and were held in cold storage by a dealer or processor. For a person on board a vessel for which a Federal commercial or charter vessel/headboat permit for the South Atlantic snapper-grouper fishery has been issued, the sale and purchase provisions of the commercial closure for golden tilefish would apply regardless of whether the fish are harvested in State or Federal waters, as specified in 50 CFR 622.43(a)(5)(ii).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds that the need to immediately implement this action to close the commercial sector for golden tilefish constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), as such procedures would be unnecessary and contrary to the public interest. Such procedures would be unnecessary because the rule itself has been subject to notice and comment, and all that remains is to notify the public of the closure.

Allowing prior notice and opportunity for public comment is contrary to the public interest because of the need to immediately implement this action to protect the fishery since the capacity of the fishing fleet allows for rapid harvest of the quota. Prior notice and opportunity for public comment would require time and would potentially result in a harvest well in excess of the established quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

This action is taken under 50 CFR 622.43(a) and is exempt from review under Executive Order 12866.

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

Dated: March 4, 2011.

Margo Schulze-Haugen,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

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