State citation	Title/subject	State effective date	EPA approval date	Additional explanation/ § 52.2063 citation
*	*	*	*	*
Subchapter B.—Emissions of NO_X From Stationary Internal Combustion Engines				
Section 145.111	Applicability	12/11/04	September 29, 2006. *[Insert page number where the document begins].*	New Section.
Section 145.112	Definitions	12/11/04	September 29, 2006. *[Insert page number where the document begins].*	New Section.
Section 145.113	Standard Requirements	12/11/04	September 29, 2006. *[Insert page number where the document begins].*	New Section.
Subchapter C.—Emissions of NO_X From Cement Manufacturing				
Section 145.141	Applicability	12/11/04	September 29, 2006. *[Insert page number where the document begins].*	New Section.
Section 145.142	Definitions	12/11/04	September 29, 2006. *[Insert page number where the document begins].*	New Section.
Section 145.143	Standard requirements	12/11/04	September 29, 2006. *[Insert page number where the document begins].*	New Section.
*	*	*	*	*

* * * * *

[FR Doc. E6–15988 Filed 9–28–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0543; FRL–8092–3]

Flufenoxuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flufenoxuron in or on apple, grape, pear, orange, and livestock commodities. BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 29, 2006. Objections and requests for hearings must be received on or before November 28, 2006, 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–2005–0543. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mark Suarez, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0120; e–mail address: *suarez.mark@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document

through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e–CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*

C. Can I File an Objection or Hearing Request?

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. 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–2005–0543 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 28, 2006.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2005–0543, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of April 19, 2006 (71 FR 20097) (FRL–7769–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E4943) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.623 be amended by establishing tolerances for residues of the insecticide flufenoxuron, 1-[4-(2-chloro-α,α,α-trifluoro-p-tolyloxy)-2-fluorophenyl]-3-(2,6-difluorobenzoyl)urea, in or on apple at 1 parts per million (ppm), pear at 1 ppm, orange at 0.3 ppm, orange oil at 60 ppm, grape at 0.2 ppm, raisin at 0.8 ppm, meat at 0.3 ppm, cattle, meat byproducts at 1.5 ppm, cattle, fat at 6 ppm, milk at 0.6 ppm, and milk, fat at 3 ppm. That notice included a summary of the petition prepared by BASF Corporation, the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

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....''

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 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for tolerances for residues of flufenoxuron, in or on apple (0.50 ppm); grape (0.70 ppm); grape, raisin (2.0 ppm); cattle, meat (0.10 ppm); cattle, fat (4.5 ppm); cattle, meat byproducts (0.50 ppm); goat, meat (0.10 ppm); goat, fat (4.5 ppm); goat, meat byproducts (0.50 ppm); horse, meat (0.10 ppm); horse, fat (4.5 ppm); horse, meat byproducts (0.50 ppm); sheep, meat (0.10 ppm); sheep, fat (4.5 ppm); sheep, meat byproducts (0.50 ppm); milk (0.20 ppm); milk, fat (4.0 ppm); orange (0.30 ppm); orange, oil (60 ppm); and pear (0.50 ppm). EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the toxic effects caused by flufenoxuron 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.epa.gov/opprd001/factsheets*.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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 level of concern (LOC). 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://wwwepa.gov/oppfead1/trac/science*.

A summary of the toxicological endpoints for flufenoxuron used for human risk assessment is shown in Table 1 of this unit:

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

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	An end point of concern attributed to single dose effect was not identified in the database.		
Acute Dietary (General population including infants and children)	An end point of concern attributed to single dose effect was not identified in the database.		
Chronic Dietary (All populations)	NOAEL= 3.75 mg/kg/day ..... UF = 100 Chronic RfD = 0.0375 mg/kg/day	FQPA SF = 1X ..... cPAD = chronic RfD/FQPA SF = 0.0375 mg/kg/day	2-Generation Reproduction Toxicity–Rat LOAEL = 14.33/16.0 (M/F) mg/kg/day based on decreased body weights during lactation during days 4-21
Oral–All Durations (Residential)	NOAEL= 3.75 mg/kg/day	LOC for MOE = 100	2-Generation Reproduction Toxicity–Rat LOAEL = 14.33/16.0 (M/F) mg/kg/day based on decreased body weights during lactation during days 4-21
Dermal–All Durations (Occupational/Residential)	Oral study ..... NOAEL= 3.75 mg/kg/day (dermal absorption rate = 100%)	LOC for MOE = 100 (Occupational). LOC for MOE = 100 (Residential)	2-Generation Reproduction Toxicity–Rat LOAEL = 14.33/16.0 (M/F) mg/kg/day based on decreased body weights during lactation during days 4-21
Inhalation–All Durations (Occupational/Residential)	Oral study ..... NOAEL= 3.75 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational). LOC for MOE = 100 (Residential)	2-Generation Reproduction Toxicity –Rat LOAEL = 14.33/16.0 (M/F) mg/kg/day based on decreased body weights during lactation during days 4-21
Cancer (oral, dermal, inhalation)	''Not likely to be carcinogenic to humans''		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. There are currently no tolerances established (40 CFR 180) for the residues of flufenoxuron. Risk assessments were conducted by EPA to assess dietary exposures from flufenoxuron 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 one-day or single exposure.

No such effects were identified in the toxicological studies for flufenoxuron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues and 100% crop treated were assumed for all commodities.

iii. *Cancer*. Flufenoxuron is classified as ''Not Likely to be Carcinogenic to Humans'' based on lack of evidence of carcinogenicity in both rats and mice carcinogenicity studies and thus an exposure assessment pertaining to cancer risk is unnecessary.

2. *Dietary exposure from drinking water*. There is no expectation that residues from flufenoxuron use on imported commodities would occur in surface or ground water sources of drinking water. No drinking water assessment was conducted.

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).

Flufenoxuron is not registered for use on any sites that would result in residential exposure.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to flufenoxuron and any other substances and flufenoxuron 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 flufenoxuron 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA 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 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased susceptibility for flufenoxuron in the developmental toxicity study in rats. No adverse effects were observed in either dams or offspring at the limit dose. Although fetal external examination data were not provided in the study report and have been requested, their absence does not affect the current risk assessment. Evidence of increased susceptibility was observed in the developmental toxicity study in rabbits. Specifically, decreased fetal weight was observed in the absence of maternal toxicity; however, fetal effects were observed at the limit dose, and the NOAEL, which is one order of magnitude lower, is considered well characterized and protective of this high-dose effect. In the 2-generation reproduction study, increased susceptibility of offspring was observed in the form of decreased body weight, since this effect was observed at a lower dose than the maternal NOAEL. However, a NOAEL for this effect in offspring was also observed, and it is considered protective of any effects at the offspring LOAEL. Based on this analysis, there is no concern for increased susceptibility of offspring following exposure to flufenoxuron. If adverse effects are observed after submission of fetal external examination data for the developmental toxicity study in rats, this conclusion may be revised.

3. *Conclusion*. There is a complete toxicity database for flufenoxuron and exposure data are complete or are estimated based on data that reasonably account for potential exposures.

The establishment of tolerances for flufenoxuron on imported commodities include consideration of the fact that: There are no residual uncertainties concerning pre- and post-natal toxicity and no neurotoxicity concerns; the chronic dietary (food + drinking water) exposure assessment is a conservative assessment that is based on reliable data and will not underestimate exposure/risk; there is no potential for drinking water exposure from the proposed use on imported commodities; there is no potential for residential exposure. Additionally, the EPA evaluated the quality of the toxicology and exposure data; and, based on these data, concluded that the FQPA SF be reduced to 1x. The recommendation was based on the following:

i. There is no evidence of increased susceptibility in the developmental study in rats.

ii. In the rabbit developmental study, there is evidence of increased susceptibility; however, the effects are well characterized and clear NOAELs and LOAELs are established. Since the effects occurred at the limit dose, the delayed fetal growth may be considered a high dose effect.

iii. In the 2-generation reproduction study in rat, there is evidence for the increased susceptibility; however, the effects were well characterized, clear NOAELs and LOAELs were established for offspring toxicities, and the endpoints were used for risk assessment. Therefore, there is no residual uncertainty for pre- and/or post-natal susceptibility.

iv. The toxicological database is complete for FQPA assessment.

v. The chronic dietary food exposure assessment utilizes proposed tolerance level residues and assumes 100% CT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Because an endpoint of concern attributable to a single dose was not identified for flufenoxuron, it 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 exposure to flufenoxuron from food will utilize 14% of the cPAD for the U.S. population, 23% of the cPAD for all infants (<1 year), and 63% of the cPAD for children 1-2 years. There are no residential uses for flufenoxuron that result in chronic residential exposure to flufenoxuron. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk, Intermediate-term risk*. Flufenoxuron is not registered for use on any sites that would result in residential or drinking water exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. Based on lack of evidence of carcinogenicity in both rats and mice carcinogenicity studies, the chemical is considered as ''not likely to be carcinogenic 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 and to infants and children from aggregate exposure to flufenoxuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate HPLC/ultraviolet (UV) method (SAMS 432-3) and liquid chromatography (LC)/mass spectrometry (MS)/MS method (BASF Method 544/0) are available for collecting data on flufenoxuron residues in/on plant commodities. The limit of quantification (LOQ) for flufenoxuron in/on plant commodities is 0.05 ppm for the HPLC/UV method and 0.01 ppm for the LC/MS/MS method. Method SAMS 432-3, which is also the proposed enforcement method for plant commodities, has been radio-validated and undergone a successful independent laboratory validation (ILV) trial. As a successful ILV trail has already been conducted, the method has been forwarded to the Analytical Chemistry Branch of the Biological and Economics Analysis Division (ACB/BEAD) for a petition method validation (PMV) (Memo, J. Tyler, 8/10/05; DP# 320112).

Adequate HPLC/UV methods are also available for collecting data on flufenoxuron residues in milk (Method SAMS 486-1) and livestock tissues (Method SAMS 457-2). The validated LOQ for flufenoxuron is 0.01 ppm in milk, 0.3 ppm in fat, and 0.1 ppm in other tissues. Method SAMS 486-1, which is the proposed enforcement method for milk, does not require radio-validation (due to the similarity between the extraction procedures in the proposed method and the extraction procedures used in the metabolism studies) and has undergone a successful ILV. This method has been forwarded to ACB/BEAD for a PMV trial (Memo, J. Tyler, 8/10/05; DP# 320112).

B. International Residue Limits

There are currently no established or proposed Canadian, Mexican or Codex maximum residue limits (MRLs) for flufenoxuron.

C. Response to Comments

A private citizen responded to PP 8E4943. Comments were received on April 19, 2006 objecting to the allowance of any residues of flufenoxuron on food commodities. One comment was received from a private citizen who opposed the authorization to sell to any pesticide that leaves a residue on food. The Agency has received this same comment from this commenter on numerous previous occasions and rejects it for the reasons previously stated. (January 7, 2005, 70 FR 1349, 1354; FRL–7691–4).

V. Conclusion

Therefore, the tolerances are established for residues of flufenoxuron, 1-[4-(2-chloro-α,α,α-trifluoro-p-tolyloxy)-2-fluorophenyl]-3-(2,6-difluorobenzoyl)urea, in or on apple (0.50 ppm); grape (0.70 ppm); grape, raisin (2.0 ppm); cattle, meat (0.10 ppm); cattle, fat (4.5 ppm); cattle, meat byproducts (0.50 ppm); goat, meat (0.10 ppm); goat, fat (4.5 ppm); goat, meat byproducts (0.50 ppm); horse, meat (0.10 ppm); horse, fat (4.5 ppm); horse, meat byproducts (0.50 ppm); sheep, meat (0.10 ppm); sheep, fat (4.5 ppm); sheep, meat byproducts (0.50 ppm); milk (0.20 ppm); milk, fat (4.0 ppm); orange (0.30 ppm); orange, oil (60 ppm); and pear (0.50 ppm).

The petitioner is to provide an amended analytical method, as the current method is not adequate for tolerance enforcement in/on plant commodities because confirmatory HPLC/UV analysis is not sufficiently distinct from the primary analytical method. The petitioner should revise the method to include a confirmatory analysis using LC/MS/MS, which has been shown to adequately detect and quantify flufenoxuron in BASF Method 544/0. In addition, although a successful ILV trial was conducted on HPLC/UV method SAMS 458- 1 using fat samples, this method is distinct from SAMS 457-2 and is only for the analysis of fat. Therefore, a separate ILV trial should be conducted on Method SAMS 457-2 using samples of liver and muscle. Any proposed HPLC/UV method must also be revised to include directions for a confirmatory analysis using an analytical method that is distinct from the primary analytical method. In addition, radio-labeled method validation data are required for the proposed enforcement method using tissue samples from the goat metabolism study to ensure that the method will adequately extract endogenous flufenoxuron residues.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866 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). 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 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 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. 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 section 408(n)(4) of FFDCA. 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.

VII. Congressional Review Act

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 20, 2006.

James Jones,

Director, 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 180.623 is added to read as follows:

§ 180.623 Flufenoxuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide, flufenoxuron, 1-[4-(2-chloro-α,α,α-trifluoro-p-tolyloxy)-2-fluorophenyl]-3-(2,6-difluorobenzoyl)urea, in or on the following food commodities.

Commodity	Parts per million
Apple[1]	0.50
Cattle, fat[1]	4.5
Cattle, meat[1]	0.10
Cattle, meat byproducts[1]	0.50
Goat, fat[1]	4.5
Goat, meat[1]	0.10
Goat, meat byproducts[1]	0.50
Grape[1]	0.70
Grape, raisin[1]	2.0
Horse, fat[1]	4.5
Horse, meat[1]	0.10
Horse, meat byproducts[1]	0.50
Milk	0.20
Milk, fat[1]	4.0
Orange[1]	0.30
Orange, oil[1]	60
Pear[1]	0.50
Sheep, fat[1]	4.5
Sheep, meat[1]	0.10
Sheep, meat byproducts[1]	0.50

[1]There are no U.S. registrations as of September 30, 2006.

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

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

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

[FR Doc. E6–15931 Filed 9–28–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0480; FRL–8092–4]

Soybean Oil, Ethoxylated; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of soybean oil, ethoxylated; when used as an inert ingredient in a pesticide chemical formulation. Cognis Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of soybean oil, ethoxylated.

DATES: This regulation is effective September 29, 2006. Objections and requests for hearings must be received on or before November 28, 2006, 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–2006–0480. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Bipin Gandhi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8380; e-mail address: *gandhi.bipin@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:

- 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 provides 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this ''**Federal Register**'' document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing