

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.

VIII. 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: December 6, 2005.

Donald R. Stubbs,

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), 346a and 371.

■ 2. Section 180.560 is amended by revising paragraph (a) to read as follows:

§ 180.560 Cloquintocet-mexyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of cloquintocet-mexyl (acetic acid, [(5-chloro-8-quinolinyl)oxy]-, 1-methylhexyl ester)(CAS No. 99607-70-2) and its acid metabolite (5-chloro-8-quinolinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients pinoxaden (wheat or barley) or clodinafop-propargyl (wheat only) in a 1:4 ratio of safener to active ingredient in or on the following food commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, hay	0.1
Barley, straw	0.1
Wheat, forage	0.1
Wheat, grain	0.1
Wheat, hay	0.1
Wheat, straw	0.1

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0276; FRL-7746-5]

Bifenazate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of bifenazate in or on tart cherries and soybeans. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on tart cherries and soybeans. This regulation establishes maximum permissible levels for residues of bifenazate in these food commodities. The tolerance will expire and is revoked on December 31, 2009.

DATES: This regulation is effective December 16, 2005. Objections and requests for hearings must be received on or before February 14, 2006.

ADDRESSES: To submit a written objection or hearing request follow the

detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2005-0276. All documents in the docket are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This 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: Marcel Howard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6784; e-mail address: howard.marcel@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 and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

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 combined residues of the miticide bifentazate, 1-methylethyl-2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, expressed as bifentazate, in or on tart cherries at 5.0 parts per million (ppm); soybean seed at 1.5 ppm; soybean hulls at 20 ppm; soybean meal at 3.5 ppm; and soybean refined oil at 20 ppm. These tolerances will expire and are revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 of the FFDCA 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) of the 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 the 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. . . ."

Section 18 of the 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 of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Bifentazate on Tart Cherries and Soybeans and FFDCA Tolerances

The state of Utah petitioned EPA to allow use of bifentazate on tart cherries to control phytophagous spider mites. EPA has determined that Utah tart cherry growers are likely to suffer significant economic losses due to pest infestation without use of bifentazate. Data submitted indicate that effective control has not been achieved using current registered products. In addition, the primary pesticide used for mite control in the past, propargite, has been relabeled for post-harvest use only. Bifentazate is necessary to prevent crop losses in the current year and to ensure tree vitality in the next year.

In a separate action, the state of Delaware petitioned EPA to allow use of bifentazate on soybeans to control two spotted spider mites. According to the applicant, there are two registered products, dimethoate and chlorpyrifos, which have some miticidal activity and are recommended for spider mite control in Delaware soybeans. EPA has determined that, in the event of hot, dry weather, mite populations could cause significant economic losses to soybean growers in Delaware, even in light of these alternatives.

EPA determined that bifentazate can be used with a reasonable certainty of no harm to humans or to the environment. Thus, EPA has authorized

under FIFRA section 18 the use of bifentazate on tart cherries for control of phytophagous spider mites in Utah, and on soybeans for control of two spotted spider mites in Delaware. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of bifentazate in or on tart cherries and soybeans. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA 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 this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on December 31, 2009, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on tart cherries and soybeans 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 these tolerances at the time of that application. EPA will take action to revoke these tolerances 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 bifentazate meets EPA's registration requirements for use on tart cherries and soybeans or whether a permanent tolerance for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of bifentazate by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Utah and Delaware to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for bifentazate, 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 of the FFDCA 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) of the 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 bifenazate and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for combined residues of bifenazate in or on tart cherries at 5.0 ppm; soybean seed at 1.5 ppm; soybean hulls at 20 ppm; soybean meal at 3.5 ppm; and soybean refined oil at 20 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 (SF).

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 x 10⁶ 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 bifenazate used for human risk assessment is shown in the following Table 1:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants, children, and females 13-50 years old)	An acute dietary endpoint was not selected based on the absence of an endpoint of concern attributed to a single dose		
Chronic Dietary (All populations)	NOAEL = 1.0 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.01 mg/kg/day	1-Year Dog Feeding Study LOAEL = 8.9/10.4 mg/kg/day [M/F] based on changes in hematological and clinical chemistry parameters, and histopathology in bone marrow, liver, and kidney
Incidental Oral, Short-Term (1 to 30 days) (Residential)	Oral study NOAEL = 10 mg/kg/day	LOC for MOE ≤ 100 (Residential)	Rat Developmental Study maternal LOAEL = 100 mg/kg/day based on clinical signs, decreased body weight and food consumption during the dosing period
Incidental Oral, Intermediate-Term (30 days to 6 months) (Residential)	Oral study NOAEL = 0.9 mg/kg/day	LOC for MOE ≤ 100 (Residential)	90-Day Subchronic Dog Study LOAEL = 10.4/10.7 mg/kg/day [M/F] based on changes in hematologic parameters
Short-, Intermediate-, and Long-Term Dermal (1 to 30 days, 30 days to 6 months, and 6 months to lifetime) (Residential)	Dermal study NOAEL = 80 mg/kg/day	LOC for MOE ≤ 100 (Residential)	21-Day Dermal Toxicity Study in Rats LOAEL = 400 mg/kg/day based on decreased body weight and food consumption, hematologic effects, increased spleen weight, and extramedullary hemopoiesis in the spleen

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term Inhalation (1 to 30 days) (Residential)	Oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE ≤ 100 (Residential)	Rat Developmental Study LOAEL = 100 mg/kg/day based on decreased body weight and food consumption
Intermediate-Term Inhalation (30 days to 6 months) (Residential)	Oral study NOAEL = 0.9 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE ≤ 100 (Residential)	90 Day Dog Feeding Study LOAEL = 10.4/10.7 mg/kg/day [M/F] based on changes in hematologic parameters
Long-Term Inhalation (6 months to lifetime) (Residential)	Oral study NOAEL = 1.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE ≤ 100 (Residential)	1-Year Dog Feeding Study LOAEL = 8.9/10.4 mg/kg/day [M/F] based on changes in hematological and clinical chemistry parameters, and histopathology in bone marrow, liver, and kidney
Cancer (oral, dermal, inhalation)	Bifenazate is classified as "not likely" to be a human carcinogen		

*The reference to the FQPA SF refers to any additional SF retained due to concerns of FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.572) for the combined residues of bifentazate, in or on a variety of raw agricultural commodities. Tolerances on primary crops range from 0.1 ppm to 35 ppm on pome fruit, fruiting vegetable, cucurbit vegetable, tree nut, nectarine, peach, plum, grape, strawberry, cotton, hops, okra, peppermint, and spearmint. Tolerances have also been established in milk, ruminant meat, and ruminant meat byproducts at 0.02 ppm. Bifenazate is a selective miticide which controls the motile stage of mites either by direct contact or through contact with foliar residues. Risk assessments were conducted by EPA to assess dietary exposures from bifentazate in food as follows:

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. As indicated in Table 1 above, toxicological data for bifentazate do not identify any dose to the chemical which triggers a toxic effect based on an acute dose. As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population, to infants, to children or to the subpopulation females 13-50 years old. Therefore, there is no acute reference dose (aRfD) or acute population-adjusted dose (aPAD) for the general

population or females 13-50 years old. An acute aggregate risk assessment was not performed because no acute risk is expected.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption 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 chronic dietary exposure analysis was based on tolerance level residues excluding tomato and soybean (average field trial residues was assumed for these crops) and average percent crop treated information. DEEM™ (Version 7.76) default processing factors were used for some commodities. The analyses also included the chronic surface water point estimate generated using the Tier 1 model First Index Reservoir Screening Tool (FIRST) which assumed that 87% of the basin is cropped and 100% of the cropped area treated at the maximum rate (surface water chronic point estimate was greater than the ground water point estimate).

iii. *Cancer.* Bifenazate has been classified as "not likely" to be a human carcinogen.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the FFDCFA 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 pursuant to section 408(f)(1) 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. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as is required by FFDCFA section 408(b)(2)(E) and authorized under FFDCFA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCFA 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; and 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) of the FFDCFA, EPA may require registrants to submit data on PCT.

The Agency used average PCT information for several commodities.

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 bifentazate may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for bifentazate in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates

are made by reliance on simulation or modeling taking into account data on the physical characteristics of bifentazate.

The Agency uses the FIRST or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will generally use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to bifentazate they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the EECs of bifentazate for chronic exposures are estimated to be 6.4 parts per billion (ppb) for surface water and <0.001 ppb for ground 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).

Bifentazate is currently registered for use on the following residential non-dietary sites: Ornamentals and non-bearing fruit trees. The risk assessment was conducted using the following exposure assumptions: Only short-term dermal and short-term inhalation exposure are expected for homeowner applicators. Post-application exposure is anticipated to be negligible and was not assessed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCFA 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 bifentazate and any other substances and bifentazate 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 bifentazate 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/>.

C. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCFA 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* Developmental toxicity and reproductive toxicity studies performed with bifentazate yield no qualitative or quantitative toxicity evidence of increased susceptibility among rats and rabbits during *in utero* exposure or during postnatal exposure.

3. *Conclusion.* There is a complete toxicity data base for bifentazate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the lack of increased susceptibility and the completeness of the toxicity and exposure databases, EPA has concluded that the additional 10X safety factor for children's health can be reduced to 1X.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the

Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to bifentazate in drinking water (when considered along with other sources of

exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of bifentazate on drinking water as a part of the aggregate risk assessment process.

1. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to bifentazate from food will utilize 36% of the cPAD for the U.S. population, 72% of the cPAD for all infants (< 1 year old) and 84% of the cPAD for children 1–2 years old. Based on the use pattern, chronic residential exposure to residues of bifentazate is not expected. In addition, despite the potential for chronic dietary exposure to bifentazate in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of bifentazate in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BIFENTAZATE

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.01	36	6.4	<0.001	230
All infants (<1 year old)	0.01	72	6.4	<0.001	26
Children (1-2 years old)	0.01	84	6.4	<0.001	21
Children (3-5 years old)	0.01	78	6.4	<0.001	25
Children (6-12 years old)	0.01	52	6.4	<0.001	47
Youth (13-19 years old)	0.01	33	6.4	<0.001	200
Adults (20-49 years old)	0.01	31	6.4	<0.001	250
Adults (50 + years old)	0.01	30	6.4	<0.001	270
Females (13-49)	0.01	35	6.4	<0.001	260

2. *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).

Bifentazate is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for bifentazate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,672 for U.S. population, 1,741 for youth 13-19 years old, 1,820 for adults 20-49 years old, 1,849 for adults 50+ years old, and 1,684 for females 13-49 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate

exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of bifentazate in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO BIFENAZATE

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	1,672	100	6.4	<0.001	3,200
Youth (13-19 years old)	1,741	100	6.4	<0.001	3,000
Adults (20-49 years old)	1,820	100	6.4	<0.001	3,300
Adults (50 + years old)	1,849	100	6.4	<0.001	3,500
Females (13-49 years old)	1,684	100	6.4	<0.001	2,700

3. 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). Though residential exposure could occur with the use of bifenazate, only short-term exposures are expected for homeowner applicators. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Aggregate cancer risk for U.S. population.* Bifenazate is classified as “not likely” to be a human carcinogen. Thus, a quantification of human cancer risk has not been performed.

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 bifenazate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) 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

Canada, Codex, and Mexico do not have maximum residue limits for residues of bifenazate in or on the proposed crops. Therefore, harmonization is not an issue.

VI. Conclusion

Therefore, time-limited tolerances are established for combined residues of bifenazate, 1-methylethyl-2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate and

diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, expressed as bifenazate, in or on tart cherries at 5.0 ppm; soybean seed at 1.5 ppm; soybean hulls at 20 ppm; soybean meal at 3.5 ppm; and soybean refined oil at 20 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number EPA–HQ–OPP–2005–0276 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 February 14, 2006.

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 issue(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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A.1., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number EPA–HQ–OPP–2005–0276, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances under section 408 of the FFDCA. 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 FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (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 the 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.

IX. 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: December 1, 2005.

Donald R. Stubbs,
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), 346a and 371.

■ 2. Section 180.572 is amended by alphabetically adding commodities in the table in paragraph (b) to read as follows:

§ 180.572 Bifenazate; tolerance for residues.

* * * * *
(b) * * *

Commodity	Parts per million	Expiration/revocation date
Cherry, tart	5.0	12/31/09
* * *	*	*
Soybean, hulls ..	20	12/31/09
Soybean, meal ..	3.5	12/31/09

Commodity	Parts per million	Expiration/revocation date
Soybean, refined oil	20	12/31/09
Soybean, seed ..	1.5	12/31/09
* * * * *	* * * * *	* * * * *

[FR Doc. 05-24137 Filed 12-15-05; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA-HQ-OPPT-2005-0047; FRL-7732-6]

RIN 2070 AC61

TSCA Inventory Update Reporting Partially Exempted Chemicals List Addition of Certain Aluminum Alkyl Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to amend the Toxic Substances Control Act (TSCA) section 8(a) Inventory Update Reporting (IUR) regulations by adding 10 aluminum alkyl chemicals to the list of chemical substances in § 710.46(b)(2)(iv) which are exempt from reporting processing and use information required by § 710.52(c)(4). EPA has determined that the IUR processing and use information for these chemicals is of low current interest. Manufacturers and importers of the chemicals listed in § 710.46(b)(2)(iv) must continue to report manufacturing information.

DATES: This direct final rule is effective on February 14, 2006 without further notice, unless EPA receives adverse comment by January 17, 2006. If, however, EPA receives adverse comment, EPA will publish a **Federal Register** document to withdraw the direct final rule before the effective date.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2005-0047, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov/>. Follow the on-line instructions for submitting comments.

- **Agency Website:** <http://www.epa.gov/edocket/>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

- **E-mail:** oppt.ncic@epa.gov.
- **Mail:** Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Hand Delivery:** OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number EPA-HQ-OPPT-2005-0047. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2005-0047. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.epa.gov/edocket/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, [regulations.gov](http://www.regulations.gov), or e-mail. The EPA EDOCKET and the [regulations.gov](http://www.regulations.gov) websites are "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL-7181-7).

Docket: All documents in the docket are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic

public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the OPPT Docket, EPA Docket Center, EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744, and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566-0280.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Susan Sharkey, Project Manager, Economics, Exposure and Technology Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-8789; e-mail address: sharkey.susan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you manufacture (defined by statute at 15 U.S.C. 2602(7) to include import) chemical substances, including inorganic chemical substances, subject to reporting under the Inventory Update Rule (IUR) at 40 CFR part 710. Any use of the term "manufacture" in this document will encompass import, unless otherwise stated.

Potentially affected entities may include, but are not limited to:

Chemical manufacturers and importers subject to IUR reporting, including chemical manufacturers and importers of inorganic chemical substances (NAICS codes 325, 32411).