beginning actual construction) whether a significant net emissions increase will occur at the major stationary source (i.e., the second step of the process) is contained in the definition in paragraph (b)(3) of this section. Regardless of any such preconstruction projections, a major modification results if the project causes a significant emissions increase and a significant net emissions increase.

* * * * *

(b) * * *

(3) * * *

(iii) * * *

(*b*) The increase or decrease in emissions did not occur at a Clean Unit except as provided in paragraphs (x)(8) and (y)(10) of this section.

* * * * *

(20) *Fugitive emissions* means those emissions which could not reasonably pass through a stack, chimney, vent, or other functionally equivalent opening.

* * * * *

(41) * * *

(ii) * * *

(*b*) Shall include fugitive emissions to the extent quantifiable, and emissions associated with startups, shutdowns, and malfunctions; and

* * * * *

(*d*) In lieu of using the method set out in paragraphs (a)(41)(ii)(*a*) through (*c*) of this section, may elect to use the emissions unit's potential to emit, in tons per year, as defined under paragraph (b)(4) of this section.

* * * * *

(48) * * *

(i) * * *

(*a*) The average rate shall include fugitive emissions to the extent quantifiable, and emissions associated with startups, shutdowns, and malfunctions.

* * * * *

(ii) * * *

(*a*) The average rate shall include fugitive emissions to the extent quantifiable, and emissions associated with startups, shutdowns, and malfunctions.

* * * * *

(iii) For a new emissions unit, the baseline actual emissions for purposes of determining the emissions increase that will result from the initial construction and operation of such unit shall equal zero; and thereafter, for all other purposes, shall equal the unit's potential to emit.

(iv) For a PAL for a stationary source, the baseline actual emissions shall be calculated for existing electric utility steam generating units in accordance with the procedures contained in paragraph (b)(48)(i) of this section, for other existing emissions units in accordance with the procedures contained in paragraph (b)(48)(ii) of this section, and for a new emissions unit in accordance with the procedures contained in paragraph (b)(48)(iii) of this section.

* * * * *

(i) * * *

(1) * * *

(vii) The source or modification would be a major stationary source or major modification only if fugitive emissions, to the extent quantifiable, are considered in calculating the potential to emit of the stationary source or modification and the source does not belong to any of the following categories:

(*a*) Coal cleaning plants (with thermal dryers);

(*b*) Kraft pulp mills;

(*c*) Portland cement plants;

(*d*) Primary zinc smelters;

(*e*) Iron and steel mills;

(*f*) Primary aluminum ore reduction plants;

(*g*) Primary copper smelters;

(*h*) Municipal incinerators capable of charging more than 250 tons of refuse per day;

(*i*) Hydrofluoric, sulfuric, or nitric acid plants;

(*j*) Petroleum refineries;

(*k*) Lime plants;

(*l*) Phosphate rock processing plants;

(*m*) Coke oven batteries;

(*n*) Sulfur recovery plants;

(*o*) Carbon black plants (furnace process);

(*p*) Primary lead smelters;

(*q*) Fuel conversion plants;

(*r*) Sintering plants;

(*s*) Secondary metal production plants;

(*t*) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;

(*u*) Fossil-fuel boilers (or combination thereof) totaling more than 250 million British thermal units per hour heat input;

(*v*) Petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels;

(*w*) Taconite ore processing plants;

(*x*) Glass fiber processing plants;

(*y*) Charcoal production plants;

(*z*) Fossil fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input;

(*aa*) Any other stationary source category which, as of August 7, 1980, is being regulated under section 111 or 112 of the Act; or

* * * * *

(r) * * *

(6) * * *

(iii) The owner or operator shall monitor the emissions of any regulated NSR pollutant that could increase as a result of the project and that is emitted by any emissions unit identified in paragraph (r)(6)(i)(*b*) of this section; and calculate and maintain a record of the annual emissions, in tons per year on a calendar year basis, for a period of 5 years following resumption of regular operations after the change, or for a period of 10 years following resumption of regular operations after the change if the project increases the design capacity or potential to emit that regulated NSR pollutant at such emissions unit.

(iv) If the unit is an existing electric utility steam generating unit, the owner or operator shall submit a report to the Administrator within 60 days after the end of each year during which records must be generated under paragraph (r)(6)(iii) of this section setting out the unit's annual emissions during the calendar year that preceded submission of the report.

* * * * *

(aa) * * *

(4) * * *

(i) * * *

(*d*) The PAL shall include fugitive emissions, to the extent quantifiable, from all emissions units that emit or have the potential to emit the PAL pollutant at the major stationary source.

* * * * *

[FR Doc. 2011–6670 Filed 3–29–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0097; FRL–8867–7]

Sodium Ferric Ethylenediaminetetraacetate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of sodium ferric ethylenediaminetetraacetate (EDTA) in or on all food commodities when applied as a molluscicide and used in accordance with good agricultural practices. W. Neudorff GmbH KG submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from

the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium ferric EDTA under the FFDCA.

DATES: This regulation is effective March 30, 2011. Objections and requests for hearings must be received on or before May 31, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0097. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: John Fournier, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0169; e-mail address: *fournier.john@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 get electronic access to other related Information?

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0097 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before May 31, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0097, by one of the following methods:

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

II. Background and Statutory Findings

In the **Federal Register** of September 30, 2010 (75 FR 60452) (FRL–8837–2), 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 tolerance petition (PP 9F7668) by W. Neudorff GmbH KG, An der Mühle 3, Postfach 1209, 31860 Emmerthal, Germany (c/o Walter G. Talarek, P.C., 1008 Riva Ridge Dr., Great Falls, VA 22066–1620). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of sodium ferric EDTA. This notice referenced a summary of the petition prepared by the petitioner, W. Neudorff GmbH KG, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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." Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider "available information

concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

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 and considered its validity, completeness, and reliability and the relationship of this information 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.

A. Overview of Sodium Ferric EDTA

The pesticidal active ingredient, sodium ferric EDTA, is a molluscicide that has historically been used to control terrestrial slugs and snails in agriculture and on ornamental landscaping. The compound is comprised of iron in a sodium chelate. This chelate forms a soluble, complex molecule with iron ions, inactivating the ions so that they cannot normally react with other elements or ions to produce precipitates or scale. In this form, the iron is more bioavailable than in other mineral sources (Ref. 1). Bioavailability of iron is an essential quality of sodium ferric EDTA as the iron in this compound is responsible for controlling slugs and snails. That is, when slugs or snails ingest sodium ferric EDTA, the iron in the compound interacts with hemocyanin, a copper-based respiratory protein common to the blood of mollusks and responsible for their oxygen transport. This interaction with hemocyanin causes suffocation and eventually results in the death of slugs and snails. Iron does not have this interaction, however, in organisms that do not use hemocyanin for oxygen transport (*e.g.,* mammals).

Iron is a necessary nutrient for all mammals and other vertebrates because it is a component of hemoglobin, the oxygen transport protein found in red blood cells of vertebrates. It is the most abundant element on Earth and, as such, can be found in most soil and water. It is an essential nutrient listed as Generally Recognized as Safe (GRAS) by the Food and Drug Administration (FDA) for direct addition to food (21 CFR 184.1375) and is added to commonly consumed, fortified foods such as enriched flour, bread, pasta, and grains. Sodium Ferric EDTA is allowed as a direct food additive by the FDA and is used as a source of iron for nutritional fortification in foods such as powdered meal replacements, flavored milk, and fruit-flavored beverages (Ref. 2), as well as soy, fish, teriyaki, and hoisin sauces (Ref. 3). The compound is also a common constituent of many cosmetic products and, despite being present at much higher concentrations than those found in sodium ferric EDTA end-use pesticide products used for control of slugs and snails, has an extensive history of safe use as an agricultural fertilizer.

In 2008, EPA registered the first sodium ferric EDTA-containing product for control of slugs and snails. EPA assessed the risks to human health and concluded that, when sodium ferric EDTA was used in accordance with widespread and commonly recognized practices, no unreasonable adverse effects on the environment were expected (Ref. 4). At the time of this initial sodium ferric EDTA registration, the applicant did not petition EPA to establish a tolerance or tolerance exemption because all uses were non-food. On December 6, 2009, however, EPA was petitioned by W. Neudorff GmbH KG to establish an exemption from the requirement of a tolerance for residues of sodium ferric EDTA in or on all food commodities. Accordingly, EPA has completed a risk assessment of mammalian toxicology data submitted in support of this request. The overall conclusions from these data are described in Unit III.B., while more in-depth synopses of the study results can be found in the risk assessment and Biopesticides Registration Action Document provided as references in Unit IX. (Refs. 5 and 6).

B. Biochemical Pesticide Human Health Assessment Data Requirements

1. *Acute toxicity.* Tier I acute toxicity studies of technical grade sodium ferric EDTA (Slugkil MP, containing 71.42% sodium ferric EDTA) showed that the active ingredient is a Toxicity Category III (slightly toxic) compound via the oral and dermal routes of exposure, a Toxicity Category III (slightly irritating) compound via the dermal and eye routes of exposure, and a Toxicity Category IV (practically nontoxic) compound for inhalation exposure. Moreover, sodium ferric EDTA is not a dermal sensitizer. Given the results of these studies, no additional toxicity (*i.e.,* Tiers II or III) or residue data are required to support food uses of this biochemical active ingredient. These acute toxicity studies confirm sodium ferric EDTA's low toxicity profile.

i. The acute oral median lethal dose (LD_{50}) for sodium ferric EDTA in rats was greater than 2,000 milligrams per kilogram (mg/kg) and confirmed low toxicity through oral exposure (Master Record Identification Number (MRID No.) 47942507). Sodium Ferric EDTA is classified as Toxicity Category III for acute oral toxicity.

ii. The acute dermal LD_{50} for sodium ferric EDTA in rats was greater than 2,000 mg/kg, which confirmed low dermal toxicity (MRID No. 47942508). Sodium Ferric EDTA is classified as Toxicity Category III for acute dermal toxicity.

iii. The acute inhalation median lethal concentration (LC_{50}) for sodium ferric EDTA in rats was greater than 2.75 milligrams per liter (mg/L) and showed practically no inhalation toxicity (MRID No. 47942512). Sodium Ferric EDTA is classified as Toxicity Category IV for acute inhalation toxicity.

iv. A primary eye irritation study showed that exposure to sodium ferric EDTA will cause temporary, mild eye irritation (MRID No. 47942509). Accordingly, EPA has determined that sodium ferric EDTA is Toxicity Category III for primary eye irritation.

v. A primary dermal irritation study showed that exposure to sodium ferric EDTA is slightly irritating (MRID No. 47942510) and a skin sensitization study showed that sodium ferric EDTA is not a sensitizer to the skin (MRID No. 47942511). Accordingly, EPA has determined that sodium ferric EDTA is Toxicity Category III for dermal irritation.

2. *Subchronic toxicity.*—i. Submission of 90-day oral toxicity data was waived by EPA because the acute oral toxicity study demonstrated sodium ferric EDTA's low toxicity (LD_{50} >2,000 .mg/kg). In their waiver rationale, the petitioner also cited information from EPA's 2008 sodium ferric EDTA Biopesticides Registration Action Document (BRAD):

> No references for feeding studies using sodium ferric EDTA were located in the published literature. Rats fed low mineral diets with or without calcium disodium EDTA for four months had reduced weight gain, but their general condition was comparable to that of controls (Ref. 7). Rats fed 1%, 5%, or 10% disodium salt of EDTA for 90 days had significantly lower food consumption and weight gain than controls (Ref. 8). Hematology was comparable among all groups, except that prothrombin time was increased in the 10% group. The only significant necropsy finding was pale livers in the 10% group.

Mice fed 3,750 or 7,500 ppm trisodium EDTA for 103 weeks had no treatment-related clinical signs, and gross and microscopic pathology were unremarkable (Ref. 9). A companion study conducted by NCI using rats produced the same results (Ref. 9). In a 12-month feeding study using dogs, Oser et al (1963) found no significant changes in hematology or urinalysis parameters, and no abnormal gross or microscopic findings in groups receiving up to 250 mg/kg body weight/day of calcium disodium EDTA (Ref. 10).

The information cited above refers to feeding studies using sodium EDTA and calcium disodium EDTA. The Agency has assessed the toxicity profile of these and other EDTA salts (Refs. 11 and 12), and concluded that they are closely related. This information sufficed for the assessment of toxicological risk characterization of sodium ferric EDTA.

Additionally, iron is an essential nutrient listed as GRAS by the FDA, and both iron and sodium ferric EDTA are allowed as direct food additives to increase the nutritional content of food and food supplements. Sodium Ferric EDTA is also used in agriculture as a fertilizer. Given all of this information, EPA concluded that no subchronic oral toxicity is expected when this compound is used in accordance with good agricultural practices.

ii. Submission of 90-day dermal toxicity data was waived by EPA because acute guideline studies demonstrated that sodium ferric EDTA has low dermal toxicity (LD_{50} >2,000 mg/kg), is a slight dermal irritant, and is not a dermal sensitizer. Repeated dermal exposure, under conditions of product use at a concentration that could be toxic, is not anticipated.

iii. Submission of 90-day inhalation data was waived by EPA because the acute inhalation toxicity study demonstrated sodium ferric EDTA's lack of toxicity (Toxicity Category IV). Repeated inhalation exposure, under conditions of product use at a concentration that could be toxic, is not anticipated.

3. *Developmental toxicity and mutagenicity.* Acceptable waiver requests were submitted to address the data requirements for Developmental toxicity and Mutagenicity (OPPTS 870.3700). The Agency concluded that humans are regularly exposed to iron found abundantly in nature and from the use of sodium ferric EDTA as fertilizer. No negative effects of sodium ferric EDTA have been reported because of its low toxicity and low water solubility, which decreases its absorption in the intestine. Moreover, the active ingredient is not a mutagen nor is it related to any known classes of mutagens. After considering the aforementioned information and the extensive history of use of sodium ferric EDTA in agriculture and food without deleterious effects, EPA waived the requirement to submit developmental toxicity and mutagenicity data.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* The primary route of sodium ferric EDTA exposure to the general population will be through consumption of food; however, there is no reason to expect that practical use of sodium ferric EDTA, in accordance with good agricultural practices, will constitute any significant hazard.

Sodium Ferric EDTA is comprised of iron in a sodium chelate. Iron is abundant in nature, an essential nutrient, and listed as GRAS for direct addition to food (21 CFR 184.1375). Sodium Ferric EDTA is regarded as safe for use as a dietary supplement to increase iron bioavailability and prevent iron deficiency. In humans, iron is an essential nutrient that is vital to the processes by which cells generate energy. It is available to animals from food derived from other animals and plants.

When sodium ferric EDTA is ingested, the chelate holds the iron in the stomach until pH rises in the upper small intestine. As pH rises, the strength of the complex progressively diminishes, allowing exchange with other metals and iron for absorption. Iron dissociates from the EDTA moiety and is released in the duodenum prior to absorption. Only a very small fraction of the sodium ferric EDTA complex (less than 1%) is absorbed intact. Intact EDTA metal complexes are rapidly excreted; they do not accumulate or undergo biotransformation (Ref. 13).

European Food Safety Authority Panel on Food Additives and Nutrient Sources added to Food (2010) concluded that, when sodium ferric EDTA is used in food supplements at levels that provide 22.3 milligrams (mg) of iron/day for adults and 11.1 mg of iron/day for children, the use of sodium ferric EDTA as a source of iron in foods is of no safety concern as long as it does not lead to an exposure of EDTA above 1.9 mg/kg/day.

Exposure to EDTA and salts of EDTA already occurs through certain FDA-approved uses as food additives, in sanitizing solutions, and in pharmaceutical products, or through their use in soaps, shampoos, or cosmetics. EDTA has also been administered safely under medical supervision as treatment for heavy metal poisoning. The results of toxicity testing and information found in public literature indicate that there is no risk to human health from residues of sodium ferric EDTA in food crops. Furthermore, residues from the formulations in agricultural use sites (certified limits <4% by weight) and residential use sites (<1% of typical formulations) are not likely to exceed levels currently consumed in commonly eaten foods. In addition, the use of EDTA and EDTA salts in pesticide products is expected to result in much lower exposure than the FDA-regulated use of these compounds, as well as lower exposure than their use in pharmaceuticals or cosmetic products.

The concentration of iron needed for good plant growth is below the concentration needed by animals for good cellular functioning. In agriculture, iron sodium chelate is used as micronutrient fertilizer at much higher concentrations than those present in sodium ferric EDTA-containing pesticide products, which are labeled for maximum application rates of below 25 mg of sodium ferric EDTA per square foot. The use of sodium ferric EDTA in pesticides is expected to result in much lower exposure than through its use in plant fertilizers, pharmaceutical products, or cosmetic products. Based on review and evaluation of available information, EPA concludes that there is a reasonable certainty of no harm from residues of sodium ferric EDTA when applied as a molluscicide and used in accordance with good agricultural practices.

2. *Drinking water exposure.* No significant drinking water exposure or residues are expected to result from the use of sodium ferric EDTA as a molluscicide. The active ingredient is intended for use directly on food commodities or the soil around crops and is not to be applied directly to water. If used in accordance with EPA-approved labeling and good agricultural practices, sodium ferric EDTA is not likely to accumulate in drinking water. Overall, exposures from residues in drinking water are unlikely and are not expected to pose a quantifiable risk due to environmental fate of sodium ferric

EDTA and lack of residues of toxicological concerns.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure of the general population, including infants and children, is limited based on the use patterns of sodium ferric EDTA. The end use products containing sodium ferric EDTA are granules or pellets that do not produce any dust and are applied directly to the ground. Therefore, it is unlikely that there will be any dermal or inhalation exposure when the product is applied according to the label use directions. Furthermore, sodium ferric EDTA was demonstrated to be practically non-toxic (Toxicity Category IV) to rats in an acute dermal toxicity guideline study (MRID 45848104) and practically non-toxic (Toxicity Category IV) to rats in an acute inhalation toxicity guideline study (MRID 45848105). Non-dietary exposures are not expected to pose any quantifiable risk to the general population.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

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

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) 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 unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Based on the results of the toxicological data discussed in Unit III.B., as well as all other available information, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of sodium ferric EDTA. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion based on the low level of toxicity of the compound, the minimal exposure from application/use of sodium ferric EDTA as a molluscicide, and the already widespread exposure through use as a fertilizer and food additive without any reported adverse effects on human health. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for sodium ferric EDTA.

VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of sodium ferric EDTA. Therefore, an exemption is established for residues of sodium ferric EDTA in or on all food commodities when applied as a molluscicide and used in accordance with good agricultural practices.

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11. U.S. EPA. 2004. Recommendation for Tolerance Reassessment for Ethylenediaminetetraacetic Acid (EDTA) and various ammonium, calcium, copper, iron, potassium, manganese, sodium and zinc salts of EDTA. Memorandum from K. Boyle to B. Shackleford dated January 28, 2004.
12. U.S. EPA. 2004. Ethylenediaminetetraacetic acid (EDTA) and the salts of EDTA: Science Assessment Document for Tolerance Reassessment. Memorandum from E. Reaves to K. Boyle dated January 26, 2004.
13. European Food Safety Authority Panel on Food Additives and Nutrient Sources added to Food 2010. Scientific opinion on the use of ferric sodium EDTA as a source of iron added for nutritional purposes to foods for the general population (including food supplements) and to foods for particular nutritional uses. *EFSA Journal* 8(1):1414.

X. 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children From Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

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

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

XI. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 17, 2011.

Steven Bradbury,

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 180.1302 is added to subpart D to read as follows:

§ 180.1302 Sodium Ferric Ethylenediaminetetraacetate (EDTA); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sodium ferric EDTA in or on all food commodities when applied as a molluscicide and used in accordance with good agricultural practices.

[FR Doc. 2011–7465 Filed 3–29–11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 160

[USCG–2011–0076]

RIN 1625–AB60

Inflatable Personal Flotation Devices

AGENCY: Coast Guard, DHS.

ACTION: Direct final rule; request for comments.

SUMMARY: By this direct final rule, the Coast Guard is harmonizing structural and performance standards for inflatable recreational personal flotation devices (PFDs) with current voluntary industry consensus standards. This direct final rule also slightly modifies regulatory text in anticipation of a future rulemaking addressing the population for which inflatable recreational PFDs are approved, but does not change the current affected population.

DATES: This rule is effective September 26, 2011 unless an adverse comment, or notice of intent to submit an adverse comment, is either submitted to our online docket via *http://www.regulations.gov* on or before May 31, 2011 or reaches the Docket Management Facility by that date. If an adverse comment, or notice to submit an adverse comment, is received by May 31, 2011, we will withdraw this direct final rule and publish a timely notice of withdrawal in the **Federal Register.** The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register on September 26, 2011.

ADDRESSES: You may submit comments identified by docket number USCG–