MAJOR MILESTONES IN LEAD NAAQS REVIEW—Continued

Major milestones	Completed/future target date(s)
Second Draft SP and Second Draft Human Health and Ecological Risk Assessment Reports for CASAC and Public Comment.	Mid-June 2007.
CASAC Meeting on Second Draft SP and Second Draft Human Health and Ecological Risk Assessment Reports.	Late July 2007.
Complete Final SP and Final Human Health and Ecological Risk Assessment Reports	Late September 2007.
Publish Proposal Notice in FEDERAL REGISTER	Late February 2008.
Final Promulgation Notice Signed by Administrator	September 1, 2008.

List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: February 23, 2006.

Jeffrey S. Clark,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. E6–3225 Filed 3–7–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA–4091; FRL–8042–4]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; VOC and NO_X RACT Determinations for Twenty-Six Individual Sources; Partial Withdrawal of Proposed Rule for Three Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Partial withdrawal of proposed rule.

SUMMARY: On April 18, 2000, EPA published a proposed rule (65 FR 20788) to approve reasonably available control technology (RACT) determinations submitted by the Pennsylvania Department of Environmental Protection (DEP) for twenty-six major sources of nitrogen oxides (NO_X) and/or volatile organic compounds (VOC). In separate final rules, EPA has already approved the RACT determinations for ten of the twenty-six sources covered by the April 18, 2000 proposed rule. In the rules portion of today's **Federal Register**, EPA is approving the RACT determinations for an additional thirteen of twenty-six sources covered by the April 18, 2000 proposed rule. EPA is hereby withdrawing its April 18, 2000 proposed rule with regard to the remaining three sources. The April 18, 2000 (65 FR 20788) proposed rule is being withdrawn with regard to Doverspike Brothers Coal Co., Hedstrom Corporation, and the thermal coal dryers at EME Homer City, LP. These three formerly RACT-subject sources have been permanently shut down and the Pennsylvania DEP has indicated to EPA that no RACT need be approved for them.

DATES: *Effective Date:* The proposed rule for Doverspike Brothers Coal Co., Hedstrom Corporation, and the thermal coal dryers at EME Homer City published at 65 FR 20788 is withdrawn as of March 8, 2006.

FOR FURTHER INFORMATION CONTACT: Marcia L. Spink, (215) 814–2104, or by e-mail at *spink.marcia@epa.gov.*

SUPPLEMENTARY INFORMATION: See the information provided in the proposed rule located in the Proposed Rules section of the April 18, 2000 **Federal Register** (65 FR 20788). EPA is withdrawing the proposed rule for only three sources, namely, Doverspike Brothers Coal Co., Hedstrom Corporation and the thermal coal dryers at EME Homer City, LP. These formerly RACT-subject sources have been permanently shut down and the Pennsylvania DEP has indicated to EPA that no RACT need be approved for them. The other actions in the April 18, 2000 **Federal Register** are not affected.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 28, 2006.

William Early,

Acting Regional Administrator, Region III.

[FR Doc. 06–2149 Filed 3–7–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0325; FRL–7750–8]

Ethylenediaminetetraacetic Acid Chemicals: Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Agency is proposing to establish 16 new and amend three existing exemptions from the requirement of a tolerance for residues of various ethylenediaminetetraacetic acid (EDTA) chemicals in or on raw agricultural commodities when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This regulation eliminates the need to establish a maximum permissible level for residues of these EDTA chemicals.

DATES: Comments, identified by docket identification (ID) number EPA–HQ–OPP–2005–0325, must be received on or before May 8, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2005–0325, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *Agency Website*: EDOCKET, EPA's electronic public 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.
- *Mail*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460–0001, Attention: Docket ID Number EPA–HQ–OPP–2005–0325.

• *Hand Delivery*: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number EPA–HQ–OPP–2005–0325. 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–OPP–2005–0325. 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.regulations.gov/*, 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 regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, 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 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 the EPA Docket Center homepage at*http://www.epa.gov/epahome/dockets.html.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. 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, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or 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: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; e-mail address: *boyle.kathryn@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 regulations.gov, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

C. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What is the Agency's Authority for Taking this Action?

This proposed rule is issued under section 408 of FFDCA, 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170). Section 408(e) of FFDCA authorizes EPA to establish, modify, or revoke tolerances, or exemptions from the requirement of a tolerance for residues of pesticide chemicals in or on raw agricultural commodities and processed foods.

III. What Action is the Agency Taking?

The Agency is proposing to establish 16 new and amend three existing tolerance exemptions for several EDTA chemicals. Currently, there are three tolerance exemptions for EDTA chemicals in 40 CFR 180.910: Disodium

zinc ethylenediaminetetraacetate dihydride, ethylenediaminetetraacetic acid, and ethylenediaminetetraacetic acid, tetrasodium salt. These exemptions are being amended to reflect a common nomenclature, add CAS Reg. Nos., and/or a 5% limitation of all EDTA chemicals in the pesticide product.

The tolerance exemptions for the tetrasodium salt and the disodium zinc are considered to be for both the hydrated and anhydrous forms. Thus, three of the new tolerance exemptions are for the hydrated forms of the tetrasodium salt and the disodium zinc salt.

The EDTA chemicals are a group of man-made chelating (binding) agents with a preferred affinity for heavier metals such as lead, mercury, cadmium, zinc, and aluminum. EDTA's ability to complex, bind, and remove such metals is used commercially to either promote or inhibit chemical reactions, depending on the application. EDTA has also been used under medical supervision to treat heavy metal poisoning. Large doses of EDTA (or one of its salts) function to scavenge the heavy metals from the body. EDTA preferentially binds with the heavy metal present with the resultant complex then being excreted.

The EDTA chemicals which are the subject of this proposed rule, the nomenclature which will be used and the CAS Reg. Nos. are in the Table below. These chemicals were selected based on information in the Agency's files which indicate use in pesticide products applied to food-use sites.

EDTA Chemical	CAS Reg. No.
Ethylenediaminetetraacetic acid (EDTA)	60–00–4
Ethylenediaminetetraacetic acid (EDTA) calcium disodium salt	62–33–9
Ethylenediaminetetraacetic acid (EDTA) disodium copper (II) salt	14025–15–1
Ethylenediaminetetraacetic acid (EDTA) disodium copper (II) salt, dihydrate	61916–40–3
Ethylenediaminetetraacetic acid (EDTA) disodium copper (II) salt, trihydrate	73637–19–1
Ethylenediaminetetraacetic acid (EDTA) disodium manganese (II) salt	15375–84–5
Ethylenediaminetetraacetic acid (EDTA) disodium manganese (I) salt, dihydrate	73637–20–4
Ethylenediaminetetraacetic acid (EDTA) disodium salt	139–33–3
Ethylenediaminetetraacetic acid (EDTA) disodium salt, dihydrate	6381–92–6
Ethylenediaminetetraacetic acid (EDTA) disodium zinc salt	14025–21–9
Ethylenediaminetetraacetic acid (EDTA) disodium zinc salt, dihydrate	73513–47–0
Ethylenediaminetetraacetic acid (EDTA) monosodium salt	17421–79–3
Ethylenediaminetetraacetic acid (EDTA) sodium iron (III) salt	15708–41–5
Ethylenediaminetetraacetic acid (EDTA) sodium salt	7379–28–4
Ethylenediaminetetraacetic acid (EDTA) tetrapotassium salt	5964–35–2
Ethylenediaminetetraacetic acid (EDTA) tetrasodium salt	64–02–8
Ethylenediaminetetraacetic acid (EDTA) tetrasodium salt, tetrahydrate	13235–36–4
Ethylenediaminetetraacetic acid (EDTA) tetrasodium salt, trihydrate	67401–50–7
Ethylenediaminetetraacetic acid (EDTA) tripotassium salt	17572–97–3

IV. 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. The nature of the toxic effects caused by these EDTA chemicals are summarized in this unit.

The data considered in this assessment included information located by the Office of Pesticide Programs on the internet, studies conducted by the National Toxicology Program (NTP) and the National Cancer Institute (NCI), several work products produced by the Cosmetic Ingredient Review, several evaluations by the World Health Organization, and articles from open literature. The Agency's overall conclusions are as follows; however, greater detail on the Agency's review and evaluation of these EDTA chemicals are in the EDTA Science Assessment, which is posted as a support document in the docket for this action (*see http://www.regulations.gov/*). It is noted that the Agency's review and evaluation covered a large group of 25 EDTA chemicals in which the available data from all of the chemicals was ''pooled'' for use as surrogate data.

As a group, the EDTA chemicals are not acutely toxic via the oral route of exposure. They are mild skin irritants and severe eye irritants.

Mutagenicity studies such as the mouse lymphoma study were negative for EDTA and its salts except for a few positive tests when administered with sterile distilled water. Genotoxicity studies for EDTA and its salts were

mixed positive and negative results, depending on assay type and cell type.

Trisodium EDTA was tested in a 2–year carcinogenicity study by the NCI. Their conclusions indicated that there were no compound-related signs of chemical toxicity, and tumor incidence was not related to treatment. This study was re-evaluated in 2003 with the conclusion that ''there is no concern for EDTA with regard to carcinogenicity.''

The Agency has evaluated 15 of the EDTA chemicals through the use of structure-activity-relationship (SAR) assessments. With one exception, these evaluations indicate no absorption of the EDTA chemicals through the skin, but predicted good absorption through the lungs and GI tract. The exception was EDTA, *per se*, which is expected to be absorbed through all routes of exposure. The Team performing the SARs indicated a low to moderate concern for human health effects. All concerns noted were considered to be due to the chelation and eventual excretion of metals such as calcium, magnesium, iron, and zinc in the mammalian body.

Other reviews indicate that EDTA is not totally absorbed when ingested. Various sources rate the absorption as poor to good with the upper limit on absorption being defined numerically as 20%. Elimination occurs mainly by the kidneys (95%) with some (5%) via the bile.

Various EDTA chemicals have been tested in repeated dose toxicity studies which included doses of up to 5% of the diet. Only diarrhea and lowered food consumption were reported in animals given 5% disodium EDTA. Taken together, all of the repeated dose toxicity studies reviewed indicate that the greatest risk in the mammalian body will occur when the EDTA attempts to scavenge the trace metals used and required by the body. The repeated conclusion of the various studies is that rats fed a low percent of an EDTA chemical in the diet with adequate minerals showed no signs of toxicity. The various developmental studies indicate that developmental effects will occur if the EDTA chemicals remove the necessary trace metals from the maternal body, so that none are available for the developing fetus.

The Agency's review and evaluation of EDTA and its various salts indicates that adverse effects occur only in the presence of mineral deficiencies. In fact, the toxic effects of EDTA are considered to be related to metal deficiencies, especially a deficiency of zinc. However, two critical pieces of information informed the Agency's evaluation of EDTA. Two developmental toxicity studies were performed using disodium EDTA. The Agency has reviewed the toxicological literature on both of these studies. In one study, rats were maintained on de-ionized water (water containing no trace minerals) and a semi-purified diet, and housed in nonmetallic caging. The test animals displayed both maternal and developmental effects. In another very similar study, rats that were maintained on tap water displayed no such effects. Thus, the availability of trace metals, particularly zinc, in the diet and drinking water work to prevent deficiencies.

Thus, test animals can consume large amounts of EDTA (up to 5% of the diet) with no adverse effects, provided that the trace metals needed by the body, are also included in the diet.

V. 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 additive uses*. EDTA is used extensively as a food additive to sequester trace metals that catalyze the oxidation of oils, vitamins, and unsaturated fats that cause rancidity, flavor changes, and discoloration. For the calcium disodium salt of EDTA an acceptable daily intake of 2.5 milligram/kilogram (mg/kg) was established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1973.

In the U.S., in food the permissible levels of the calcium disodium salt of EDTA, as specified in 21 CFR 172.120, range from 25 to 800 ppm. Use of calcium disodium EDTA as a food additive is permitted for direct addition to food for human consumption, as long as (1) the quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food, and (2) any substance intended for use in or on food is of appropriate food grade, and is prepared and handled as a food ingredient.

Disodium EDTA can also be used as a food additive for direct addition to food for human consumption in specified foods, as specified under 21 CFR 172.135.

For sodium iron EDTA, a provisional maximum tolerance daily intake of 0.8 mg/kg/bodyweight was established by the Joint FAO/WHO Committee.

In 1981, an article in a toxicology journal reported that the maximum human consumption of EDTA and its salts in foods was on the order of 0.4 mg/kg/day.

2. *Food contact surface sanitizing solutions*. The disodium and tetrasodium salts of EDTA are used in food contact surface sanitizing solutions, as specified in 40 CFR 180.940. A screening-level exposure estimate of this use was performed for the tetrasodium salt. The estimated exposure is 0.005 mg/kg/day.

3. *In pesticide products applied to agricultural crops*. The Agency is proposing to place a limitation of 5% of total EDTA in pesticide products. This limit was based on information in the Agency's files. To account for possible food residues as a result of application of an inert ingredient in a pesticide product, the Agency has developed a screening-level model for predicting dietary exposure to inert ingredients. The model assumes that the inert ingredients are used on all crops and 100% of all crops are ''treated'' with the inert ingredient. The results of the model are considered to over-estimate exposure to an inert ingredient in a pesticide product. The model is scalable and can be adjusted to account for lower percent in formulations. The scaled estimate for use of EDTA chemicals with a limitation of 5% in the formulation is 0.006 mg/kg/day.

B. Drinking Water

EDTA is a strong organic acid (approximately 1,000 times stronger than acetic acid). It has a high affinity for alkaline-earth ions (for example, calcium and magnesium) and heavy-metal ions (for example, lead and mercury). This affinity generally results in the formation of highly stable and soluble complexes. The EDTA chemicals are soluble in water, have low sorption to soil and sediments, have no significant vapor pressure, and have a biodegradation half-life of weeks to months. While EDTA chemicals are slow to degrade, aerobic biodegradation (mineralization to carbon dioxide and water) is the dominant mechanism. The rate of biodegradation of EDTA in soils is reported to vary depending upon environmental factors such as pH, temperature, soil classification, organic matter, and types and population of microbes.

There are significant releases of EDTA to the environment in domestic sewage (from use in detergents, soaps, and

cleaning products) and industrial effluents (bleaching of textiles and paper; processing of photographic material; electroplating; bottle cleaning; and industrial cleaning of pipe and tank systems). Detergent preparations are probably the predominant source of EDTA found in domestic sewage, contributing an estimated 100 micrograms/Liter (µg/L) to the total concentration of EDTA in average sewage streams, with smaller amounts probably originating from food and other consumer products.

After treatment, the effluent from sewage treatment plants is released to streams, rivers, and lakes, and is further diluted by the receiving waters. According to Toxnet (see *http://toxnet.nlm.nih.gov*) ethylenediamine tetraacetic acid has been detected in ground water (ranging from 5 to 25 µg/L), and drinking water derived from surface water (10 to 45 µg/L).

Using 45 µg/L, the estimated exposure via drinking water is 1.5 µg/kg/day or 0.0015 mg/kg/day for adult females and 4.5 µg/kg/day or 0.0045 mg/kg/day for children.

C. Other Non-Occupational

Several EDTA chemicals are used as chelating agents in cosmetics. Examples of products containing EDTA chemicals include: bubble baths, bath soaps and detergents, deodorants, facial makeups and lotions, colognes and toilet waters, hair products (shampoos, rinses, conditioners, dyes and colors), nail basecoats and undercoats, and nail creams and lotions. EDTA chemicals are also used in cleaning products and laundry detergents and to control the interactions of trace metals in pharmaceuticals, metal working, pulp and paper processing, rubber and polymer chemistry, and textile processing and dyeing.The available information indicates that the non-food uses of EDTA are more prevalent than the food-uses. The information in the Agency's files indicates that pesticide products applied to residential use sites generally contain less than 1% of EDTA in the formulated product.

Using this information on percents in formulation, the Agency has estimated short-term screening level dermal exposure estimates for EDTA chemicals using both EDTA, *per se*, and the tetrasodium salt of EDTA. Since the screening level estimates were identical for both of these chemicals, they can serve as surrogate estimates for all the EDTA chemicals. Note that inhalation exposure estimates are not used since the vapor pressure of EDTA chemicals is so low.

- For a typical cleaning product, the estimated exposure estimate is 0.028 mg/kg/day
- For a typical laundry detergent, the estimated exposure estimate is 0.0088 mg/kg/day
- For a cosmetic product, the estimated exposure is 0.0008 mg/kg/day

These modeled exposure estimates indicate that the exposures that could occur from the use of these EDTA chemicals in either residential pesticidal or consumer non-pesticidal products are less than the levels at which an adverse effect could occur.

VI. Cumulative Effects

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

Unlike other pesticide chemicals 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 ethylene diaminetetraacetic acid and its various salts. The EDTA chemicals are a structurally-related group of chemicals, that travel through the mammalian body and are excreted. For the purposes of this tolerance action, therefore, EPA has not assumed that these chemical substances 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 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/*.

VII. Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA concluded that a different margin of safety will be safe for infants and children.

EDTA chemicals are chelating agents or scavengers. Their function is to locate and then bind to metals. Many metals (iron, zinc, manganese) are required in the mammalian body in trace amounts for proper functioning of the mammalian body. Lack of these metals, and most particularly zinc, can lead to severe effects.

Various salts of EDTA have been tested in several developmental toxicity studies. Based on developmental studies in lab rodents, EDTA and salts should not posed a developmental concern. Results of a developmental study indicate no developmental effects are likely in rodents at doses up to 1,000 mg/kg/day. Adequate minerals in the diet and administration of tap water prevented possible developmental effects of EDTA during pregnancy. In a different developmental toxicity study, developmental effects observed in lab rodents were likely due to animals maintained on deionized water and a semi-purified diet, and housed in nonmetallic caging. It is unlikely that infants and children would be exposed to concentrations as high as the lab rodents studied. The maximum human consumption of EDTA and its salts in foods was reported to be on the order of 0.4 mg/kg/day. Infants and children, also, generally drink tap water instead of deionized or distilled water.

EDTA is also used therapeutically in adults and pregnant women. A therapeutic dose of 1.2 to 2.0 grams per day is generally given to adults. Information is also available indicating EDTA treatment of pregnant women is possible without affecting the development of the fetus. Treatments of EDTA to pregnant women include 75 mg/kg/day calcium disodium EDTA for 7 days and 1 gram twice a day for 3 days, under medical supervision. Healthy, normal infants were delivered 4 weeks and 8 days after chelation therapy, respectively.

EPA also believes there would be a very low exposure of infants to EDTA. First, premature or very young infants ingest only formula or breast milk. (It is generally recommended that infants not consume solid food until 4 to 6 months of age). Regulation of infant formulas is under the purview of the FDA (*www.fda.gov/fdac/features/596__baby.html*). Calcium disodium EDTA, disodium EDTA, and tetrasodium EDTA are used as direct food additives (21 CFR 172.120, 172.135, and 178.1010, respectively). However, all manufacturers of infant formula must begin with safe food ingredients, which are approved either generally as safe or approved as food additives for use in infant formula. Neither EDTA nor the salts of EDTA are currently approved by the FDA for use in infant formula. Therefore, infants consuming only infant formula or breast

milk would be exposed to very low amounts of EDTA. Second, even if young infants were to be fed some solid food, given the characteristics of EDTA and its salts, residues are not likely to be present at concentrations for potential sensitivity. Once past this several month time-period, there is no longer a concern for potential sensitivity to infants and children. Older infants, like adults, process EDTA through well understood metabolic pathways.

The comparison of two developmental toxicity studies performed using disodium EDTA clearly indicates that the presence of trace metals in the drinking water and diet, particularly zinc, work to prevent deficiencies. Based on this information concerning both toxicity and exposure, a safety factor analysis has not been used to assess the risk of ethylenediaminetetraacetic acid (EDTA) and its various salts. For the same reasons, the additional tenfold safety factor for the protection of infants and children is unnecessary.

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

Based on the available toxicity data on ethylenediaminetetraacetic acid (EDTA) and its various salts, with particular emphasis on the comparison of the findings in the two developmental toxicity studies; the reviews and evaluations conducted by NTP, NCI, and WHO; the knowledge that trace metal supplementation occurs via the food and drinking water consumed by human beings; and considering the estimated exposures of the wide-spread existing uses of ethylenediaminetetraacetic acid (EDTA) and its various salts which are less than levels at which adverse effects were noted, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of ethylenediaminetetraacetic acid (EDTA) and its various salts. EPA finds that establishing exemptions from the requirement of a tolerance for ethylenediaminetetraacetic acid (EDTA) and its various salts with the following limitation ''The concentration of all EDTA chemicals is not to exceed 5% in the formulated pesticide product'' will be safe for the general population including infants and children.

IX. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . .'' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing ethylenediaminetetraacetic acid and its various salts for endocrine effects may be required.

B. Analytical Method(s)

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.

C. Existing Exemptions

There are three existing tolerance exemptions for ethylenediaminetetraacetic acid, disodium zinc ethylenediaminetetraacetate dihydride, and ethylenediaminetetraacetic acid, tetrasodium salt in 40 CFR 180.910. These are the tolerance exemptions proposed for amendment as a result of this action. There are four existing tolerance exemptions for the disodium and tetrasodium EDTA salts in 40 CFR 180.940. These four exemptions are not the subject of this action.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance or tolerance exemption for ethylenediamine tetraacetic acid and its various salts, nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusions

Accordingly, EPA proposes to establish 16 new and amend three existing exemptions from the requirement of a tolerance for residues of various ethylenediaminetetraacetic acid (EDTA) chemicals in or on raw agricultural commodities when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. The concentration of all EDTA chemicals is not to exceed 5% in the formulated pesticide product.

XI. Statutory and Executive Order Reviews

This rule proposes to amend three existing and establish 16 new exemptions from the requirement of a tolerance under section 408(e) of FFDCA. The Agency is acting on its own initiative. 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 proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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 proposed 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). The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) Generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant impact on a substantial number of small entities. The Agency hereby certifies that this proposed action will not have significant negative economic impact on a substantial number of small entities. Establishing exemptions from the requirement of a pesticide tolerance, as is proposed, is in effect the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities. 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 proposed rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this proposed 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 proposed 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 proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: February 27, 2006.

Lois Ross,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be 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 180.910, in the table, is amended by removing the entry for Disodium zinc ethylenediaminetetraacetate dihydride; by revising the entries for ethylenediaminetetraacetic acid and ethylenediaminetetraacetic acid (EDTA) tetrasodium salt and adding alphabetically the remaining entries as set forth below to read as follows:

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

Inert Ingredient	Limits	Uses
* * * * * *	*	
Ethylenediaminetetraacetic acid (EDTA) (CAS Reg. No.60–00–4)	The concentration of all EDTA chemicals is not to exceed 5% in the formulated pesticide product.	Sequestrant
Ethylenediaminetetraaceticacid (EDTA) calcium disodium salt (CAS Reg. No.62–33–9)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) disodiumcopper (II) salt (CAS Reg. No. 14025–15–1)	Do.	Do.
Ethylenediaminetetraaceticacid (EDTA) disodiumcopper (II) salt, dihydrate(CAS Reg. No. 61916–40–3)	Do.	Do.
Ethylenediaminetetraaceticacid (EDTA) disodium copper (II) salt, trihydrate(CAS Reg. No. 73637–19–1)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) disodiummanganese (II) salt (CAS Reg. No. 15375–84–5)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) disodiummanganese (I) salt, dihydrate (CAS Reg. No. 73637–20–4)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) disodium salt(CAS Reg. No. 139–33–3)	Do.	Do.
Ethylenediaminetetraaceticacid (EDTA) disodium salt, dihydrate (CAS Reg. No. 6381–92–6)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) disodium zincsalt (CAS Reg. No. 14025–21–9)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) disodium zinc salt, dihydrate (CAS Reg. No.73513–47–0)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) monosodiumsalt (CAS Reg. No. 17421–79–3)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) sodium iron(III) salt (CAS Reg. No. 15708–41–5)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) sodium salt(CAS Reg. No. 7379–28–4)	Do.	Do.
Ethylenediaminetetraaceticacid (EDTA) tetrapotassiumsalt (CAS Reg. No. 5964–35–2)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) tetrasodium salt(CAS Reg. No. 64–02–8)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) tetrasodium salt, tetrahydrate (CAS Reg. No. 13235–36–4)	Do.	Do.
Ethylenediaminetetraaceticacid (EDTA) tetrasodium salt, trihydrate (CAS Reg. No.67401–50–7)	Do.	Do.
Ethylenediaminetetraacetic acid (EDTA) tripotassium salt (CAS Reg. No. 17572–97–3)	The concentration of all EDTA chemicals is not to exceed 5% in the formulated pesticide product.	Sequestrant
* * * * * *	*	

[FR Doc. 06–2106 Filed 3–7–06; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 745

[EPA–HQ–OPPT–2004–0126; FRL–7690–8]

Lead Hazard Information Pamphlet; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of EPA's new lead hazard information pamphlet for renovation activities, *Protect Your Family from Lead During Renovation, Repair & Painting,* for review and comment. There is an increased risk of lead-based paint poisoning during renovation activities, particularly to children under 6 years of age. To better inform families about the risks and to encourage greater public health and safety during renovation activities in target housing, EPA has developed a renovation-specific information pamphlet for families. This new pamphlet gives information on lead-based paint hazards in a home, lead testing, how to select a contractor, what precautions to take during the renovation, and proper cleanup activities. EPA is seeking comment on all aspects of the pamphlet's content and design. After reviewing the comments, EPA will publish a final version of the pamphlet that may be used to comply with the requirements of section 406(b) of the Toxic Substances Control Act (TSCA).

DATES: Comments, identified by docket identification (ID) number EPA–HQ–OPPT–2004–0126, must be received on or before April 7, 2006.

ADDRESSES: Submit your comments, identified by docket ID number EPA–HQ–OPPT–2004–0126, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *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–2004–0126. 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–2004–0126. EPA's policy is that all comments received will be included in the public docket without change and may be made available in the on-line docket at *http://www.regulations.gov*, 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 regulations.gov, or e-mail. The regulations.gov Web site is an ''anonymous access'' system, 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 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.

Docket: All documents in the docket are listed in the docket index at *http://www.regulations.gov/*. 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 the online docket at *http://www.regulations.gov/* 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: Joshua B. Novikoff, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 566–0502; e-mail address: *novikoff.joshua@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you perform renovations in target housing for compensation. Target housing is defined as any housing constructed prior to 1978, except housing for the elderly or persons with disabilities (unless any child who is less than 6 years of age resides or is expected to reside in such housing) or any 0-bedroom dwelling (40 CFR 745.103). Potentially affected entities may include, but are not limited to:

- Renovators (NAICS 236118), e.g., general building contractors/operative builders, renovation firms, individual contractors.
- Special trade contractors, e.g., carpenters (NAICS 38350), painters (NAICS 238320), drywall workers and lathers (NAICS 238310), home improvement contractors.
- Landlords (NAICS 561110), e.g., multi-family housing property management firms and owners.

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 745.82. If you have any questions regarding the applicability of