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MONSANTO COMPANY

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs.

MONSANTO COMPANY,

Defendant.

Case No. CGC-16-550128

EXHIBITS 26-32 TO:

DEFENDANT MONSANTO COMPANY'S REQUEST FOR JUDICIAL NOTICE OF U.S. ENVIRONMENTAL PROTECTION AGENCY DOCUMENTS AND FEDERAL REGISTER MATERIALS

Trial Date: June 18, 2018
Time: 9:30 a.m.
Department: 504

Exhibit 26

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Delores Barber, attest that I am the Director of the Information Technology and Resources Management Division (ITRMD) of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

Document Dated: December 3, 2008
Federal Register, Glyphosate; Pesticide Tolerances Final Rule (16 pages)

Subscribed under the penalty of perjury on this 7th day of June, 2018.

Delores Barber

Delores Barber, Director
Information Technology and Resources Management Division (ITRMD)

CERTIFICATION OF TRUE COPY

I, Wendy Blake, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

Wendy L. Blake
Associate General Counsel
General Law Office
Office of General Counsel

Date: 6/11/18

LEGAL STATUS

LEGAL STATUS

Glyphosate; Pesticide Tolerances

A Rule by the Environmental Protection Agency on 12/03/2008

DOCUMENT DETAILS

Printed version:
PDF (https://www.gpo.gov/fdsys/pkg/FR-2008-12-03/pdf/E8-28571.pdf)

Publication Date:
12/03/2008 (/documents/2008/12/03)

Agency:
Environmental Protection Agency (https://www.federalregister.gov/agencies/environmental-protection-agency)

Dates:
This regulation is effective December 3, 2008. Objections and requests for hearings must be received on or before February 2, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (/select-citation/2018/06/18/40-CFR-178) (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

Effective Date:
12/03/2008

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EPA-HQ-OPP-2007-0147
FRL-8385-7

Document Number:
E8-28571

DOCUMENT DETAILS

PUBLISHED DOCUMENT

AGENCY:

Environmental Protection Agency (EPA).

ACTION:

Final rule.

SUMMARY:

This regulation establishes new tolerances for certain plant commodities and all animal commodities, and revises other tolerances for glyphosate and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate). These changes are detailed in Unit II of this document. E.I. DuPont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES:

This regulation is effective December 3, 2008. Objections and requests for hearings must be received on or before February 2, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (/select-citation/2016/07/30/40-CFR-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-2007-0147. All documents in the docket are listed in the docket index available at http://*www.regulations.gov (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 (http://www.regulations.gov),* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-305-5704; e-mail address: *walters.vickie@epa.gov (mailto:walters.vickie@epa.gov).*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in

determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at http:/ */www.regulations.gov (http://www.regulations.gov)*, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr (http://www.epa.gov/fedrgstr)*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 (/select-citation/2016/07/30/40-CFR-180) through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr (http://www.gpoaccess.gov/ecfr)*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=346&type=usc&link-type=html)a, 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 (/select-citation/2016/07/30/40-CFR-178). To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2007-0147 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 as required by 40 CFR part 178 (/select-citation/2016/07/30/40-CFR-178) on or before February 2, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178 (/select-citation/2016/07/30/40-CFR-178), please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 (/select-citation/2016/07/30/40-CFR-2) may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0147, by one of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov (http://www.regulations.gov)*. Follow the o *N*-line instructions for submitting comments.

Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 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.

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II. Petition for Tolerance

In the **Federal Register** of May 9, 2007 (72 FR 26372 (/citation/72-FR-26372)) (FRL-8121- 5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=346&type=usc&link-type=html)a(d)(3), announcing the filing of a pesticide petition (PP 6F7146) by E.I. DuPont de Nemours and Company, DuPont Crop

Protection, Laurel Run Plaza, P.O. Box 80, Newark, DE 19714-0030. The petition requested that 40 CFR 180.364 (/select-citation/2016/07/30/40-CFR-180.364) be amended by establishing tolerances for combined residues of the herbicide glyphosate, *N*-(phosphonomethyl)glycine and its metabolite *N*-acetyl-glyphosate, *N*-acetyl-*N*-(phosphonomethyl)glycine resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate to Optimum™ GAT™ soybeans in or on the food commodities: Cattle, kidney; cattle, liver; egg, goat, kidney; goat, liver; hog, kidney; hog, liver; horse, kidney; horse, liver; poultry, meat; poultry, meat byproducts; sheep, kidney; sheep, liver; soybean, forage; soybean, hay; soybean, hulls; and soybean, aspirated grain fractions at levels already established for glyphosate alone. That notice referenced a summary of the petition prepared by E.I. DuPont de Nemours and Company, the registrant, which is available to the public in the docket, *http://www.regulations.gov (http://www.regulations.gov).* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

DuPont has requested a Section 3 registration under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") for the preplant application of the herbicides glyphosate and pyrithiobac sodium to glyphosate-tolerant soybean. The petitioner is also working to commercialize a genetically modified soybean designated as Optimum™ GAT™ soybeans. *N*-acetyl-glyphosate is produced when glyphosate is applied to Optimum™ GAT™ soybeans. As a result the petitioner is requesting that the glyphosate tolerance expression be modified from glyphosate per se to the combined residues of glyphosate and *N*-acetyl-glyphosate. This petition was filed in conjunction with Dupont's this requested change to its FIFRA registration.

Based upon review of the data submitted in support of the petition, EPA has determined that the residues of concern in these commodities are glyphosate and *N*-acetyl-glyphosate. The current tolerance expression specifies residues of glyphosate (*N* (phosphonomethyl)glycine). To address that *N*-acetyl-glyphosate was the major residue in mature Optimum™ GAT™ soybean forage, hay, and seed, the Agency concluded that it is necessary to include this compound in the tolerance expression. EPA is splitting current § 180.364(a) into paragraphs (a)(1) and (a)(2). Paragraph (a)(1) will include all of the commodities currently in paragraph (a), except for the animal commodities and the commodities grain, aspirated fractions; soybean, forage; soybean, hay; soybean, hulls; and soybean, seed, which EPA is transferring to new paragraph (a)(2). The tolerances in paragraph (a)(2) will cover application of glyphosate to non-genetically modified soybeans, genetically-modified soybeans currently in use, and Optimum™ GAT™ soybeans. Note that based on the submitted residue data on application of glyphosate to Optimum™ GAT™ soybeans, the numerical value of the current soybean and livestock tolerances do not need to be changed (only the tolerance expression is changing). Combined residues of glyphosate and *N*-acetyl-glyphosate in soybean commodities derived from glyphosate-treated Optimum™ GAT™ soybeans and livestock commodities from animals which consume only glyphosate-treated Optimum™ GAT™ soybeans will not exceed the existing tolerance level. Additionally, the change in tolerance expression will not affect the application of the tolerance to soybean commodities derived from glyphosate-treated non-genetically modified soybean and livestock commodities from animals which consumed only glyphosate-treated non-genetically modified soybean because these commodities will have only glyphosate per se residues, and not *N*-acetyl-glyphosate residues.

In the **Federal Register** of May 2, 2007 (72 FR 24188 (/citation/72-FR-24188))(FRL-8122-8), the Agency published a final rule revising the tolerance expression for glyphosate to include the dimethylamine salt of glyphosate. Because there is a potential for soybeans to be treated with product containing the dimethylamine salt of glyphosate the Agency has determined that the dimethylamine salt of glyphosate should be added to the tolerance expression for paragraph (a)(2).

Based upon review of the soybean processing studies submitted supporting the petition, EPA has determined that the currently established tolerances for the commodities grain, aspirated fractions and soybean, hulls need to be increased to 310 ppm and 120 ppm, respectively. Currently established tolerance levels for all other commodities in this rule are supported by available data.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for the combined residues of glyphosate, *N*-(phosphonomethyl)glycine and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate on the food commodities cattle, meat byproducts at 5.0 ppm; egg at 0.05 ppm; goat, meat byproducts at 5.0 ppm; grain, aspirated fractions at 310 ppm; hog, meat byproducts at 5.0 ppm; horse, meat byproducts at 5.0 ppm; poultry, meat, at 4.0 ppm; poultry, meat byproducts at 1.0 ppm; sheep, meat byproducts at 5.0 ppm; soybean, seed at 20.0 ppm; soybean, forage at 100.0 ppm; soybean, hay at 200.0 ppm, and soybean, hulls at 120 ppm and soybean, seed at 20.0 ppm. EPA's assessment of exposures and risk associated with establishing tolerances follows.

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A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by glyphosate and its metabolite *N*-acetyl-glyphosate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov (http://www.regulations.gov)* in the document entitled Petition: 6F7146. Glyphosate-Isopropylammonium and Pyrithiobac Sodium. Human Health Risk Assessment for Application to Glyphosate Tolerant Soybean; pages 7-10 in docket ID number EPA- HQ-OPP-2007-0147 and identified as document EPA-HQ-OPP-2007- 0147-0007.

The toxicological profile of glyphosate is discussed in the risk assessment referenced earlier in this section and in the risk assessment referenced in the final rule published in the **Federal Register** of December 20, 2006 (71 FR 76180 (/citation/71-FR-76180)) (FRL-8105-9) which establishes tolerances for residues of glyphosate in or on noni at 0.20 ppm; pea, dry at 8.0 ppm; safflower at 85 ppm; sunflower at 85 ppm; and vegetable, legume group 6 except soybean and pea, dry at 5.0 ppm.

Toxicological endpoints and current risk assessments for glyphosate are discussed in the risk assessment referred to in the final rule published in the **Federal Register** of December 20, 2006 (71 FR 76180 (/citation/71-FR-76180)) (FRL-8105-9) which establishes tolerances for residues of glyphosate in or on noni at 0.20 ppm; pea, dry at 8.0 ppm; safflower at 85 ppm; sunflower at 85 ppm; and vegetable, legume group 6 except soybean and pea, dry at 5.0 ppm.

1. A summary of the data submitted in support of the metabolite *N*-acetyl-glyphosate is listed below. Refer to the risk assessment available in the public docket for this rule and identified above as document EPA-HQ-OPP-2007-0147-0007 for more information.

i. An acute oral toxicity study in rats with an Acute Oral LD_{50} greater than 5,000 milligrams/kilogram (mg/kg).

ii. A 90-day subchronic oral (feeding) study, in which no systemic toxicity was observed in male and female rats at doses up to 18,000 ppm (equal to 1157/1461 mg/kg/day in males/females, respectively).

iii. *N*-acetyl-glyphosate was negative for mutagenicity in a bacterial reverse mutation assay (Ames test), an *in vitro* chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells, an *in vitro* Mammalian Cell Gene Mutation Assay in CHO cells and an *in vivo* cytogenetics (bone marrow) in mice, and a metabolism and pharmacokinetics study.

2. *N*-acetyl aminomethylphosphonic acid (*N*-acetyl-AMPA) was detected as one of the metabolites formed following oral administration of *N*-acetyl-glyphosate. It is not expected to be absorbed quickly from the gastrointestinal tract since it is a charged molecule at the physiological pH. *N*-acetyl-AMPA is expected to be less toxic than *N*-acetyl-glyphosate. Data submitted in support of this metabolite included the following:

i. An acute oral toxicity study with an LD_{50} of greater than 8,300 mg/kg.

ii. A bacterial reverse mutation assay (Ames test), in which *N*-acetyl-AMPA was not mutagenic when tested up to 5,000 microgram (µg)/plate in presence and absence of activation in *S. typhimurium* strains of TA98, TA 100, TA1535, TA1537, and in *Escheria coli* strain WP2uvrA.

iii. An *in vitro* Mammalian Chromosome Aberration Test in Human Perpherral Blood Lymphocytes, in which *N*-acetyl-AMPA was negative for the induction of structural and numerical chromosome aberrations in both the non-activated and the S9-activated test systems when tested up to 15.30 milligrams/milliliter (mg/ml).

iv. An *in vitro* Mammalian Cell Gene Mutation Test (CHO/HPRT) Test, in which *N*-acetyl-AMPA was not mutagenic at the HGPRT locus in Chinese hamster ovary cells tested up to 1,531 µg/ml in the presence and absence of metabolic activation.

v. An *in vivo* Mouse Bone Marrow Micronucleus Test, in which *N*-acetyl-AMPA resulted in no detections of chromosomal aberrations were detected in male and female mice at doses up to 2,000 mg/kg.

3. For the purpose of assessing the aggregate risk from glyphosate tolerances, EPA has assumed that *N*-acetyl-glyphosate is equally toxic to glyphosate. This conservative assumption is based on the structural similarity of *N*-acetyl-glyphosate with glyphosate; a structure activity relationships (SAR) analysis of *N*-acetyl-glyphosate with a lack or structural alerts for carcinogenicity, mutagenicity and endocrine effects; and toxicity data for *N*-acetyl-glyphosate showing low acute toxicity, low subchronic toxicity and lack of

mutagenicity, In all probability, *N*-acetyl-glyphosate is of lower toxicity than glyphosate. For example, subchronic toxicity testing with glyphosate showed no systemic toxicity in male and female rats at doses up to 400 mg/kg/day in males and females. Subchronic testing with *N*-acetyl-glyphosate showed no systemic toxicity in male and female rats at doses up to 1157/1446 mg/kg/day in males/females, respectively.

The toxicity of *N*-acetyl-AMPA is considered low and of limited concern based on the available data described above, and lack of any structural alerts.

Amendment of the glyphosate soybean and meat and milk tolerances to include *N*-acetyl-glyphosate in the tolerance expression does not result in changes in the exposure or risk estimates reported in the previous risk assessments for the reasons listed below and fully discussed in the risk assessment referenced earlier in this section.

i. The Agency has determined that *N*-acetyl-glyphosate has no greater toxicity than glyphosate and probably is of lower toxicity.

ii. The numerical value of all but two food tolerances will remain the same.

iii. The most recent dietary analysis assumed tolerance level residues and, 100% crop treated.

iv. The estimate of glyphosate levels in drinking water is based on a glyphosate use involving direct application to water at 3.75 pounds active ingredient per acre. Use of glyphosate on glyphosate-resistant soybeans will not result in higher levels in drinking water.

v. Previously calculated dietary burdens to poultry were based on alfalfa meal (400 ppm tolerance) and soybeans hulls (100 ppm tolerance) as significant contributors to the diet. Based on the latest guidance, although soybean seed, meal, and hulls are feed to poultry, soybean hulls are is no longer considered a significant contributor to poultry diets. The previously calculated dietary burdens to hog were based on alfalfa meal and barley grain (20 ppm tolerance) being significant contributors to the diet. Soybean seed and meal are fed to hogs; however, the current action does not require an increase in tolerance for soybean seed or meal. Based on these complications, the Agency concludes that the application of glyphosate to Optimum™ GAT™ soybean will not result in combined residues of glyphosate and *N*-acetyl-glyphosate (expressed as glyphosate) in poultry or hog commodities greater than the residues of glyphosate that result under the currently established glyphosate per se tolerances.

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vi. Previously calculated dietary burdens to dairy or beef cattle were based on alfalfa hay (400 ppm tolerance) being the significant contributor to the diet. The Agency concludes that the consumption of glyphosate Optimum™ GAT™ soybean will not result in combined residues of glyphosate and *N*-acetyl-glyphosate (expressed as glyphosate) in or on beef/dairy cattle commodities greater than the currently established glyphosate per se tolerances for the reasons below.

a. The high tolerance value for alfalfa hay (400 ppm) and alfalfa hay occupies 40% of the total beef/dairy cattle diet.

b. The soybean hull tolerance is only increasing from 100 to 120 ppm and soybean hulls will occupy at most 20% of the beef/dairy cattle dietary burdens.

c. Aspirated grain fractions occupy at most 5% of the beef cattle dietary burden and are not feed to dairy cattle.

Accordingly, based on the risk assessments discussed in the notice referenced above, EPA concludes that no harm will result to the general population and to infants and children from aggregate exposure to the combined residues of glyphosate and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate).

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography (HPLC) with tandem mass spectrometry (MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov (mailto:residuemethods@epa.gov).*

B. International Residue Limits

There are Codex Maximum Residue Levels (MRL) established for glyphosate (sum of glyphosate and AMPA, expressed as glyphosate) on soybean, dry at 20 ppm; edible offal (mammalian) at 5 ppm; eggs at 0.05 ppm; poultry meat at 0.05 ppm and poultry, edible offal of at 0.5 ppm. Canadian MRLs are established for glyphosate including the metabolite aminomethylphosphonic acid (AMPA) on soybean seed at 20 ppm, kidney of cattle, goats, hogs, poultry and sheep at 2.0 ppm; and liver of cattle, goats, hogs, poultry, and sheep at 0.2 ppm. A Mexican MRL of 6 ppm is established for glyphosate. The glyphosate tolerances EPA is establishing in this action differ from the tolerance expression for the CODEX, Canadian or Mexican MRLs, due to the inclusion of *N*-acetyl-glyphosate in the expression. Additionally, the EPA tolerances differ from the CODEX and Canadian MRLs in that the EPA tolerances do not include AMPA in tolerance expression. At this time, harmonization between the U.S. tolerances and the CODEX, Canadian or Mexican MRLs can not be achieved because of the inclusion of *N*-acetyl-glyphosate in the EPA tolerances is necessary to support use patterns in the United States and EPA has concluded that AMPA should not be included in the tolerance expression because it is not toxicologically significant. The petitioner is seeking registration and amendment of the tolerance expressionin other countries. This may lead to harmonization between the U.S. tolerances and the CODEX, Canadian or Mexican MRLs.

C. Response to Comments

Three commenters submitted comments in response to the notice of filing. A summary of the comments and EPA's response follows.

1. *Comment*. One commenter does not believe that DuPont has submitted sufficient toxicological data to demonstrate that *N*-acetyl-glyphosate is not of toxicological concern and that submitted data did not support the claim of equivalent toxicity between glyphosate and *N*-acetyl-glyphosate. The commenter argued that the single acute toxicity EPA relied on actually suggests that *N*-acetyl-glyphosate is more toxic than glyphosate. This commenter also believes that reproductive, developmental, and chronic and carcinogenicity data on *N*-acetyl-glyphosate should be generated and analyzed.

Another commenter expressed concern that sufficient data may not have been submitted on the metabolite *N*-acetyl-glyphosate to satisfy the requirements for EPA to establish tolerances or to support the establishment of MRLs by other countries. The first commenter expressed a similar concern that submitted

data failed to meet requirements of international authorities such as Joint FAO/WHO Meeting in Pesticide Residues (JMPR), particularly when compared to the extensive data bases required for other metabolites such as AMPA and *N*-acetyl-glufosinate.

Response. EPA does not agree with the contention that *N*-acetyl-glyphosate is more toxic than glyphosate. The Agency concluded that *N*-acetyl-glyphosate is not likely to be more toxic than glyphosate based on the available toxicity studies and Structure Activity Relationship (SAR). The available acute toxicity study with *N*-acetyl-glyphosate and glyphosate indicate low toxicity (Acute Oral LD_{50} was greater than 5,000 mg/kg bw). Both *N*-acetyl-glyphosate and glyphosate are placed in acute Tox Category IV. There was evidence of some mortality in an acute oral study with *N*-acetyl-glyphosate but not with glyphosate. However, the evidence from very high doses in this acute oral LD_{50} test suggesting that *N*-acetyl-glyphosate might be more toxic than glyphosate is outweighed by the results of subchronic tests with the two compounds. There was no evidence of systemic toxicity in 90-day dietary toxicity studying rats with *N*-acetyl-glyphosate conducted at well above the limit dose (18,000 PPM equal to 1,157/1,461 mg/kg/day in males and females, respectively). In a 90-day dietary toxicity study in rats with glyphosate at 0, 1,000, 5,000 or 20,000 ppm (equivalent to 0, 63, 317, or 1,267 mg/kg/day in males and 0, 84, 404, or 1,623 mg/kg/day in females), glyphosate caused increased serum phosphorus and potassium at all doses treated in both sexes and occurrence of high dose pancreatic lesions in males (effect was not evaluated at lower doses). Based on these findings systemic toxicity NOAEL for glyphosate can be considered as less than 1,000 ppm (equivalent to <63 mg/kg/day). Thus the subchronic study with *N*-acetyl glyphosate clearly indicates that it is less toxic than glyphosate. The available adequate battery of mutagenicity studies with *N*-acetyl glyphosate and glyphosate indicate that they are not mutagenic. The metabolism of *N*-acetyl glyphosate and glyphosate is well studied in rats. These studies indicate that both compounds are rapidly absorbed and excreted from the body and are not biosequestered. In fact, nearly all of the orally administered *N*-acetyl-glyphosate was excreted unchanged in the urine and feces. There is extensive database available on glyphosate, which indicate that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant. Based on its structural similarities with glyphosate and available data, it is reasonable to conclude that the *N*-acetyl-glyphosate is not likely to be more toxic than the parent. The Agency evaluated available information and data and concluded that additional data on *N*-acetyl-glyphosate was not needed based on the weight of evidence described above. In addition, Agency has accepted bridging data where evidence is clear in order to reduce the animal usage.

EPA also disagrees with the claim that EPA has insufficient data on *N*-acetyl-glyphosate. EPA did review larger data sets on the metabolites AMPA and *N*-acetyl-glufosinate but these larger data sets were submitted voluntarily by pesticide registrants; EPA did not require these data to be submitted. EPA's decision to review all data that was submitted whether required or not (which is something the Agency does routinely) can not be converted into an EPA determination that such data would be required to make a safety finding for a similar pesticide metabolite. For the reasons expressed above, EPA concludes it has sufficient data on *N*-acetyl-glyphosate. For similar reasons, EPA also disagrees with the commenter's suggestion that because the Joint FAO/WHO Meeting in Pesticide Residues (JMPR) reviewed larger data sets on AMPA and *N*-acetyl-glufosinate, EPA's data set on *N*-acetyl-glyphosate must be deficient. The JMPR does not have any regulatory authority to require data and the commenters do not claim that JMPR defined the toxicological data needed to make the toxicity determinations with regard to AMPA and *N*-acetyl-glufosinate. The JMPR reviewed the data voluntarily submitted; it did not make a recommendation on the data necessary to make the needed toxicity evaluation.

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2. *Comment*. One commenter argues that the higher residues of *N*-acetyl-glyphosate may be absorbed at a higher rate than glyphosate. Taking into consideration the increased absorption for *N*-acetyl-glyphosate compared to glyphosate are likely in meat, milk, poultry, and eggs due to the high values of *N*-acetyl-glyphosate that are likely in plants and the higher absorption in animals of *N*-acetyl-glyphosate (when compared to glyphosate). The commenter notes that Optimum™ GAT™ soybeans were specifically engineered to convert *N*-acetyl-glyphosate and thus is likely to result in significant amounts of *N*-acetyl-glyphosate in soybeans. As to the higher absorption in animals, the commenter references a rat metabolism study and argues that indicates that higher absorption would occur in poultry and livestock that ingest residues of *N*-acetyl-glyphosate in feed and that the higher absorption would likely result in higher residues in meat, milk, and eggs when compared with glyphosate.

Response. As the commenter stated, the rat metabolism studies indicate that *N*-acetyl-glyphosate may be absorbed at a higher rate than glyphosate. Taking into consideration the increased absorption for *N*-acetyl-glyphosate, the previously calculated livestock diets (driven by 400 ppm alfalfa hay/meal tolerances), and the previously revised guidance concerning the construction of livestock diets (changes to the percent each food feedstuff contributes to a livestock diet, livestock diets are now constructed taking in to consideration nutritional requirements), it was concluded that higher livestock tolerances are not necessary. Note that the dietary analysis assumed tolerance level residue for the livestock commodities (i.e. assumes all of the commodities feed to livestock have tolerance level residues and all livestock commodities consumed by humans have tolerance level residues).

3. *Comment*. One commenter expressed concern that the petitioner had stated its intent to increase glyphosate spray rates or change spray timing and that residue data had not be submitted to reflect levels of *N*-acetyl-glyphosate under actual use conditions.

Response. The petitioner submitted several Optimum™ GAT™ soybean magnitude-of-the-residue studies which monitored for residues of glyphosate and *N*-acetyl-glyphosate in forage and hay and soybean seed. (See document cited earlier in this unit for detailed discussion of these data). The Agency concluded that this data was acceptable and supported the proposed use pattern. The Agency also concluded that additional field trial data were not necessary and that the proposed tolerance levels discussed in Unit II of this document were acceptable. The Agency has not received an application requesting increased application rates or changes in application timing at this time. The Agency will reevaluate the need for additional magnitude-of-the-residue data if and when an application of this type is received.

4. *Comment*. A concern expressed by two of the three commenters was the possible amendment of FIFRA registration to allow higher application rates on soybeans of ALS inhibitor herbicides such as sulfonylureas already registered on soybeans or new uses of ALS inhibitor herbicides on soybeans. Such amended uses or new uses, the commenter urged, should be conditioned on the submission of additional residue data or consideration of possible effects to non-target plants and endangered species.

Response. The Agency has not received requests for increased use or new uses of ALS inhibitor pesticides on Optimum™ GAT™ soybean seed to additional herbicides at this time. The pre-plant use of pyrithiobac sodium in soybeans remained unchanged for this action. However, as discussed on page 3 of the risk assessment referenced in Section III of this document, since ALS tolerance is conferred via modification of the endogenous ALS gene such that the plant is no longer sensitive (i.e. the tolerance is not conveyed via metabolism of the herbicide), the Agency's current view is that the nature/magnitude of residues submitted in support of registration of ALS-inhibiting herbicides to nontransgenic soybean are applicable for application of these compounds to Optimum™ GAT™ soybean.

5. *Comment.* One commenter expressed a concern that the analytical method submitted may not enable simultaneous quantification of the combination of glyphosate, *N*-acetyl-glyphosate and aminomethylphosphonic acid (AMPA), all of which could be present in exported soybeans.

Response. Available information including Agency method trial confirms that proposed analytical method (high performance liquid chromatography (HPLC) with tandem mass spectrometry (MS/MS)) quantifies residues of glyphosate, *N*-acetyl-glyphosate, and AMPA in crops and animal commodities.

6. *Comment.* One commenter opposed the way the tolerance expression was written in the notice of filing and the fact that a new paragraph was being added to the tolerance expression allowing for duplicate listings of the same commodities dependent on genetic makeup.

Response. Based on the submitted comments and the available information the Agency has decided that 40 CFR 180.364 (/select-citation/2016/07/30/40-CFR-180.364)(a) will be redesignated as paragraph (a)(1) and that the current listings from newly redesignated paragraph (a)(1) for soybean and animal commodities will be transferred to new paragraph (a)(2). The revised tolerance expression deletes any reference to genetic make up. See Unit II of this document for discussion.

7. *Comment.* One commenter expressed a concern that current EPA label policy allowing the use of general terminology such as "glyphosate tolerant soybeans" would permit use of any soybean seed that satisfies the general "glyphosate tolerant" criteria if crop seed such as Optimum™ GAT™ soybean seed were commercially available, even if appropriate data have not been reviewed and tolerances granted.

Response. The EPA label policy is intended to allow the use of glyphosate on any approved glyphosate tolerant seed. The Agency does not regulate or approve the glyphosate tolerant seed, only the use of glyphosate on the crops grown from the glyphosate tolerant seed. The approval of the seed itself is handled by the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS). Information on approval of the Optimum™ GAT™ soybean seed is available in a notice published in the **Federal Register** of July 24, 2008 (73 FR 43203 (/citation/73-FR-43203)) which advised the public of their determination that a soybean line developed by Pioneer HI-Bred International, Inc., designated as transformation event 356043, which has been genetically engineered for tolerance to glyphosate and acetolactate synthase-inhibiting herbicides, is no longer considered a regulated article under their regulations governing the introduction of certain genetically engineered organisms, and the public docket established for that action by USDA/APHIS, which is available at *http://www.regulations.gov (http://www.regulations.gov)* and is identified as docket identification number APHIS-2007-019.

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8. *Comment.* One commenter expressed a concern that Optimum™ GAT™ soybeans are plants that have high levels of a new abnormal enzyme that creates new untested metabolites. The commenter referenced an article (Science, 21 May 2004, vol. 34 pp 1151-1154) which shows that the new "shuffled enzyme" (*N*-acetylate) can react with common amino acids L-aspartate, L-serine, phosphor-L-serine, L-threonine, L-glutamate, L-aspargine, and L-cysteine to form new *N*-acetylated versions of these common amino acids. The commenter stated that toxicology data may be necessary to address the safety of these *N*-acetylated metabolites.

Response. This issue concerns componets of the Optimum™ GAT™ soybean and not residues of the pesticide glyphosate and is not relevant to EPA's determination of safety under section 408 of the FFDCA. However, similar comments were received and addressed by APHIS during the course of their review of the Optimum™ GAT™ soybean seed which is fully discussed in the **Federal Register** notice of July 24, 2008

and the APHIS public docket referenced earlier in this unit. In summary APHIS reviewed available information toxicity data available for both the 356043 soybean seed and *N*-acetyl-L-aspartic acid (NAA) and determine that additional toxicological assessment was unwarranted. APHIS determined that quantification of other acetylated amino acids did not need to be measured based on the fact that the GAT4601 enzyme has different kinetic and specificity properties than the native enzymes from Bacillus licheniformis which have the ability to use additional amino acids as substrates under specific *in vitro* conditions. The study conducted with GAT4601 demonstrated the kinetic parameters could only be established for aspartate and glutamate. Additional information concerning this conclusion can be found in the APHIS public docket referenced earlier in this unit.

9. *Comment.* One commenter expressed concern that sufficient data may not have been submitted on the metabolite *N*-acetyl-glyphosate to satisfy the requirements for EPA to establish tolerances or to support the establishment of MRLs by other countries and Agencies. A second commenter expressed a similar concern that submitted data failed to meet requirements of international authorities such as Joint FAO/WHO Meeting in Pesticide Residues (JMPR), particularity when compared to the extensive databases required for other metabolites such as AMPA and *N*-acetyl-glufosinate.

Response. The Agency has determined that the submitted data discussed above and in the referenced risk assessments provided sufficient information for the Agency to make the required human safety determination required in the FFDCA and satisfy data requirements for establishment of tolerances and registration in the United States.

10. *Comment.* One commenter expressed concern that the proposed unilateral change to the glyphosate residue definition to include the new metabolite *N*-acetyl-glyphosate has significant potential to disrupt the international trade of soybeans for U.S. growers until the glyphosate residue definition is implemented globally. The commenter further noted that the data submitted to EPA may not be sufficient for other countries to modify their tolerance expressions.

Response. The petitioner submitted a summary of a metabolism study conducted with Optimum™ GAT™ soybean. This study indicated that both glyphosate and *N*-acetyl-glyphosate were significant residues in/on Optimum™ GAT™ soybean forage and straw. For mature Optimum™ GAT™ soybean seed, only *N*-acetyl-glyphosate was a significant residue (glyphosate represented a minor component of the total residue). Since *N*-acetyl-glyphosate was the major residue in mature Optimum™ GAT™ soybean forage, hay, and seed, EPA concluded that it is necessary to include this compound in the tolerance expression.

EPA believes that the new metabolite *N*-acetyl glyphosate is not likely to disrupt international trade of soybean for U.S. growers. DuPont is seeking registration in various countries. The Agency expects that the various countries will come to similar conclusion as the United States for Optimum™ GAT™ soybean and amend their tolerance expressions which will alleviate the potential trade issue. The current analytical method would detect glyphosate, AMPA and *N*-acetyl glyphosate allowing enforcement of the tolerances in other countries. Growers in the United States have the option of growing conventional soybeans or other varieties of glyphosate tolerant seed until any trade issues in other countries with Optimum™ GAT™ soybeans are resolved.

11. *Comment.* Several comments were received from a private citizen objecting to establishment of tolerances.

Response. The Agency has received similar comments from this commenter on numerous previous occasions. Refer to the **Federal Register** of March 14, 2007 (72 FR 11784 (/citation/72-FR-11784); FRL-8117-2) for the Agency's response to these objections. In addition the commenter noted that bees and turkey vultures are dying. These comments are not relevant to human safety determination which is the sole focus of tolerance actions under section 408 of the FFDCA. For informational purposes, EPA would note that pesticide effects on wildlife are addressed in the FIFRA registration process. In a honey bee contact test with glyphosate, mortality was low in all treatment levels. The results indicate that glyphosate is classified as practically nontoxic to honeybees. Although the Agency does not require testing on turkey buzzards specifically, the potential for avian mortality to glyphosate has been assessed using bobwhite quail acute oral LD_{50} study and bobwhite quail and mallard duck 8-day dietary LC_{50} studies. These data indicate that glyphosate is practically nontoxic to avian species on an acute oral basis and no more than slightly toxic on a subacute dietary basis. The potential effects to avian growth and reproduction from glyphosate have been assessed using avian reproduction studies with mallard duck and bobwhite quail. These data indicate that glyphosate is not expected to cause reproductive impairment. The commenter did not submit any information to support a revision of Agency conclusions.

V. Conclusion

Therefore, tolerances are established for combined residues of glyphosate, *N*-(phosphonomethyl)glycine and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate on the food commodities cattle, meat byproducts at 5.0 ppm; egg at 0.05 ppm; goat, meat byproducts at 5.0 ppm; grain, aspirated fractions at 310 ppm; hog, meat byproducts at 5.0 ppm; horse, meat byproducts at 5.0 ppm; poultry, meat, at 4.0 ppm; poultry, meat byproducts at 1.0 ppm; sheep, meat byproducts at 5.0 ppm; soybean, seed at 20.0 ppm; soybean, forage at 100.0 ppm; soybean, hay at 200.0 ppm, and soybean, hulls at 120 ppm as discussed in Unit II of this document.

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VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, (/executive-order/13211) entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355 (/citation/66-FR-28355), May 22, 2001) or Executive Order 13045, (/executive-order/13045) entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885 (/citation/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 (https://api.fdsys.gov/link?collection=uscode&title=44&year=mostrecent&section=3501&type=usc&link-type=html) *et seq.*, nor does it require any special considerations under Executive Order 12898, (/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 (https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=601&type=usc&link-type=html) *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, (/executive-order/13132) entitled Federalism (64 FR 43255 (/citation/64-FR-43255), August 10, 1999) and Executive Order 13175, (/executive-order/13175) entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249 (/citation/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) (Public Law 104-4 (https://api.fdsys.gov/link?collection=plaw&congress=104&lawtype=public&lawnum=4&link-type=html)).

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 (https://api.fdsys.gov/link?collection=plaw&congress=104&lawtype=public&lawnum=113&link-type=html), section 12(d) (15 U.S.C. 272 (https://api.fdsys.gov/link?collection=uscode&title=15&year=mostrecent&section=272&type=usc&link-type=html) note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 (https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=801&type=usc&link-type=html) *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 (https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=804&type=usc&link-type=html)(2).

List of Subjects in 40 CFR Part 180 (/select-citation/2016/07/30/40-CFR-180)

- Environmental protection (/topics/environmental-protection)
- Administrative practice and procedure (/topics/administrative-practice-and-procedure)
- Agricultural commodities (/topics/agricultural-commodities)
- Pesticides and pests (/topics/pesticides-and-pests)
- Reporting and recordkeeping requirements (/topics/reporting-and-recordkeeping-requirements)

Dated: November 19, 2008.

Donald R. Stubbs,

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 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=321&type=usc&link-type=html)(q), 346a and 371.

2. Section 180.364 is amended as follows:

a. By removing the entries cattle, meat byproducts; egg; goat, meat byproducts; grain, aspirated fractions; hog, meat byproducts; horse, meat byproducts; poultry, meat; poultry, meat byproducts; sheep, meat byproducts; soybean, forage; soybean, hay; soybean, hulls; and soybean, seed from the table in paragraph (a).

b. By redesignating paragraph (a) introductory text and the remainder of the table as paragraph (a)(1) and by adding paragraph (a)(2) to read as follows:

§ 180.364 Glyphosate, Tolerance for residue.

(a) * * * (1) * * *

(2) Tolerances are established for combined residues of glyphosate, *N*-(phosphonomethyl)glycine and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate on the food commodities:

Commodity	Parts per Million
Cattle, meat byproducts	5.0
Egg	0.05
Goat, meat byproducts	5.0
Grain aspirated fractions	310.0
Hog, meat byproducts	5.0
Horse, meat byproducts	5.0
Poultry, meat	4.0
Poultry, meat byproducts	1.0
Sheep, meat byproducts	5.0
Soybean, forage	100.0
Soybean, hay	200.0
Soybean, hulls	120.0
Soybean, seed	20.0

* * * * *

[FR Doc. E8-28571 (/a/E8-28571) Filed 12-2-08; 8:45 am]

BILLING CODE 6560-50-S

Exhibit 27

Pub. L. 107–295, 116 Stat. 2064; Departm nt of H m land Security Delegation N . 0170.1

■ 2. A d tem orary § 165.T08–0310 to read as follow :

165.T08–0310 afety Zone; O io River, M les 460.0 to 470.5, Cincinnati, O .

(a) *Location.* The follow ng area is a safety zone: A l w ters of the O io River, from surface to bottom beginning at m le m rker 460.0 and ending at m le m rker 470.5.

(b) *Effective Period.* This section is effective from 8 a.m to 12:30 p.m on June 27, 2009.

(d) *Regulations.* (1) In accordance w th the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port O io Valley or a designated representative.

(2) Persons or vessels requiring entry into or passage through the zone m st request perm ssion from the Captain of the Port O io Valley or a designated representative. U S. Coast Guard Sector O io Valley m y be contacted on VH Channel 13 or 16.

(3) A l persons and vessels shall com ly w th the instructions of the Captain of the Port O io Valley and designated U S. Coast Guard patrol personnel. O -scene U S. Coast Guard patrol personnel include com ssioned, w rrant, and Petty O ficers of the U S. Coast Guard.

Dated: M y 5, 2009.

A E. Tucci,

Com nder, U S. Coast Guard, Captain of the Port O io Valley, A ting.

[FR Doc. E9–14166 Filed 6–16–09; 8:45 am

BILLING CO E 4910–15–P

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 52

[R05–O R–2008–0031; FRL–8919–7]

Approval and Prom lgation of Air Q ality Im lem ntation Plans; Indiana; W thdraw l of Direct Final Rule

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Withdraw l of direct final rule.

SUM RY: Due to the receipt of an adverse com nt, the EPA is w thdraw ng the M y 5, 2009 (74 FR 20599), direct final rule approving a rule revision to extend Federally Enforceable State O erating Perm t renew l term from five years to ten years. The State of Indiana subm tted this revision as a m dification to the State Im lem ntation Plan on Decem er 19, 2007. In the direct final rule, EPA stated that if adverse com nts w re subm tted by June 4, 2009, the rule w uld be w thdraw and not take effect. O M y 19, 2009, EPA received a com nt. EPA believes this com nt is adverse and, therefore, EPA is w thdraw ng the direct final rule. EPA w ll address the com nt in a subsequent final action based upon the proposed action also published on M y 5, 2009 (74 FR 20665). EPA w ll not institute a second com nt period on this action.

DATES: The direct final rule published at 74 FR 20599 on M y 5, 2009, is w thdraw as of June 17, 2009.

FO URTHER NFO M TIO O TACT: Sam Portanova, Environm ntal Engineer, A r Perm ts Section, A r Program Branch (A –18J), U EPA Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–3189, *portanova.sam epa.gov.*

List of Subjects in 40 CFR Part 52

Environm ntal protection, A r pollution control, Carbon m noxide, Incorporation by reference, Intergovernm ntal relations, Lead, N trogen dioxide, O one, Particulate m tter, Reporting and recordkeeping requirem nts, Sulfur oxides, Volatile organic com ounds.

A thority: 42 U S.C. 7401 *et seq.*

Dated: June 4, 2009.

Walter W. Kovalick Jr.,

A ting Regional A m nistrator, Region 5.

PART 52—[AM NDED]

■ A cordingly, the am ndm nt to 40 CFR 52.770 published in the **Federal Register** on M y 5, 2009 (74 FR 20599) on page 20601 is w thdraw as of June 17, 2009.

[FR Doc. E9–14240 Filed 6–16–09; 8:45 am

BILLING CO E 6560–50–P

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 180

[EPA–HQ O P–2008–0738; FRL–8418–6]

Alkyl Am ne Polyalkoxylates; Exem tion from the Requirem nt of a Tolerance

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Final rule.

SUM RY: This regulation establishes an exem tion from the requirem nt of a tolerance for residues of alkyl am ne polyalkoxylates w en used as inert ingredients in pesticide form lations applied to grow ng crops and anim ls. The Joint Inerts Task Force (JITF), Cluster Support Team N m er 4 subm tted a petition to EPA under the Federal Food, Drug, and Cosm tic A t (FFDCA , requesting an exem tion from the requirem nt of a tolerance. This regulation elim nates the need to establish a m xim m perm ssible level for residues of alkyl am ne polyalkoxylates.

DATES: This regulation is effective June 17, 2009. O jections and requests for hearings m st be received on or before A gust 17, 2009, and m st be filed in accordance w th the instructions provided in 40 CFR part 178 (see also U it I.C. of the **SUPPLEM NTARY INFO M TIO).**

ADDRESSES: EPA has established a docket for this action under docket identification (ID) num er EPA H O P–2008–0738. A l docum nts in the docket are listed in the docket index available at *http://w regulations.gov.* A though listed in the index, som inform tion is not publicly available, e.g., Confidential Business Inform tion (CBI) or other inform tion w ose disclosure is restricted by statute. Certain other m terial, such as copyrighted m terial, is not placed on the Internet and w ll be publicly available only in hard copy form Publicly available docket m terials are available in the electronic docket at *http://w regulations.gov,* or, if only available in hard copy, at the O P Regulatory Public Docket in Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA The Docket Facility is open from 8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays. The Docket Facility telephone num er is (703) 305–5805.

FO URTHER NFO M TIO O TACT: Kerry Leifer, Registration Division (7505P), O fice of Pesticide Program , Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001; telephone num er: (703) 308–8811; e-m il address: leifer.kerry@*epa.gov.*

SUPPLEM NTARY NFO M TIO : I

I. G neral Inform tion

A Does this A tion A ply to M ?

You m y be potentially affected by this action if you are an agricultural producer, food m nufacturer, or pesticide m nufacturer. Potentially affected entities m y include, but are not lim ted to those engaged in the follow ng activities:

• Crop production (N CS code 111).

• A im l production (N CS code 112).

• Food m nufacturing (N CS code 311).

• Pesticide m nufacturing (N CS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. O her types of entities not listed in this unit could also be affected. The N rth A rican Industrial Classification System (N CS) codes have been provided to assist you and others in determ ning w ether this action m ght apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FO URTHER INFO M TIO O TACT**.

B. How Can I A cess Electronic Copies of this Docum nt?

In addition to accessing electronically available docum nts at *http://w regulations.gov*, you m y access this **Federal Register** docum nt electronically through the EPA Internet under the "**Federal Register**" listings at *http://w epa.gov/fedrgstr*. You m y also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Governm nt Printing O fice's e-CFR cite at *http://w gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

U der section 408(g) of FFDCA 21 U S.C. 346a, any person m y file an objection to any aspect of this regulation and m y also request a hearing on those objections. You m st file your objection or request a hearing on this regulation in accordance w th the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA you m st identify docket ID num er EPA H O P–2008–0738 in the subject line on the first page of your subm ssion. A l requests m st be in w iting, and m st be m iled or delivered to the H aring Clerk as required by 40 CFR part 178 on or before A gust 17, 2009.

In addition to filing an objection or hearing request w th the H aring Clerk as described in 40 CFR part 178, please subm t a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Inform tion not m rked confidential pursuant to 40 CFR part 2 m y be disclosed publicly by EPA w thout prior notice. Subm t this copy, identified by docket ID num er EPA H O P–2008–0738, by one of the follow ng m thods:

• *Federal eRulem king Portal*: *http://w regulations.gov*. Follow the on-line instructions for subm tting com nts.

• *M il*: O fice of Pesticide Program (O P) Regulatory Public Docket (7502P), Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001.

• *Delivery*: O P Regulatory Public Docket (7502P), Environm ntal Protection A ency, Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA Deliveries are only accepted during the Docket Facility's norm l hours of operation (8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays). Special arrangem nts should be m de for deliveries of boxed inform tion. The Docket Facility telephone num er is (703) 305–5805.

II. Background

In the **Federal Register** of Decem er 3, 2008 (73 FR 73644) (FRL–8386–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA 21 U S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7382) by The Joint Inerts Task Force (JITF), Cluster Support Team N m er 4 (CST 4), c/o CropLife A rica, 1156 15th Street, N , Suite 400, Washington, DC 20005, The petition requested that 40 CFR 180.920 and 40 CFR 180.930 be am nded by establishing exem tions from the requirem nt of a tolerance for residues of the inert ingredient *N,N*-Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl) C_8-C_{18} saturated and unsaturated alkylam nes; the poly(oxy-1,2-ethanediyl) content is 2–60 m les and *N,N*-Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl/oxy(m thyl-1,2-ethanediyl) C_8-C_{18} saturated and unsaturated alkylam nes; the poly(oxy-1,2-ethanediyl/oxy(m thyl-1,2-ethanediyl) content is 2-60 m les (these substances are referred to throughout this docum nt as alkyl am ne polyalkoxylates). That notice referenced a sum ry of the petition prepared by JITF, CST 4, the petitioner, w ich is available to the public in the docket, *http://w regulations.gov*. There w re no com nts received in response to the notice of filing.

This petition w s subm tted in response to a final rule of A gust 9, 2006, (71 FR 45415) in w ich the A ency revoked, under section 408(e)(1) of FFDCA the existing exem tions from the requirem nt of a tolerance for residues of certain inert ingredients because of insufficient data to m ke the determ nation of safety required by FFDCA section 408(b)(2). The expiration date for the tolerance exem tions subject to revocation w s A gust 9, 2008, w ich w s later extended to A gust 9, 2009 (73 FR 45312) to allow for data to be subm tted to support the establishm nt of tolerance exem tions for these inert ingredients prior to the effective date of the tolerance exem tion revocation.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not lim ted to, the follow ng types of ingredients (except w en they have a pesticidal efficacy of their ow): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polym rs and fatty acids; carriers such as clay and diatom ceous earth; thickeners such as carrageenan and m dified cellulose; w tting, spreading, and dispersing agents; propellants in aerosol dispensers; m croencapsulating agents; and em lsifiers. The term "inert" is not intended to im ly nontoxicity; the ingredient m y or m y not be chem cally active. Generally, EPA has exem ted inert ingredients from the requirem nt of a tolerance based on the low toxicity of the individual inert ingredients.

IV. A gregate Risk A sessm nt and Determ nation of Safety

Section 408(b)(2)(A (i) of FFDCA allow EPA to establish an exem tion from the requirem nt of a tolerance (the legal lim t for a pesticide chem cal residue in or on a food) only if EPA determ nes that the tolerance is "safe." Section 408(b)(2)(A (ii) of FFDCA defines "safe" to m an that "there is a reasonable certainty that no harm w ll result from aggregate exposure to the pesticide chem cal residue, including all anticipated dietary exposures and all other exposures for w ich there is reliable inform tion." This includes exposure through drinking w ter and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chem cal residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm w ll result to infants and children from aggregate exposure to the pesticide chem cal residue...."

EPA perform a num er of analyses to determ ne the risks from aggregate exposure to pesticide residues. First, EPA determ nes the toxicity of pesticides. Second, EPA exam nes exposure to the pesticide through food, drinking w ter, and through other

exposures that occur as a result of pesticide use in residential settings.

Consistent w th section 408(b)(2)(D) of FFDCA and the factors specified in section 408(b)(2)(D) of FFDCA EPA has review d the available scientific data and other relevant inform tion in support of this action. EPA has sufficient data to assess the hazards of and to m ke a determ nation on aggregate exposure for the petitioned-for exem tion from the requirem nt of a tolerance for residues of alkyl am ne polyalkoxylates w en used as inert ingredients in pesticide form lations applied to grow ng crops or food-producing anim ls. EPA's assessm nt of exposures and risks associated w th establishing tolerances follow .

A Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, com leteness, and reliability as w ll as the relationship of the results of the studies to hum n risk. EPA has also considered available inform tion concerning the variability of the sensitivities of m jor identifiable subgroups of consum rs, including infants and children.

A kyl am ne polyalkoxylates are not acutely toxic by the oral and derm l routes of exposure, or via inhalation under norm l use conditions. Concentrated m terials are generally corrosive, eye and skin irritants and m y be derm l sensitizers. There is no evidence that alkyl am ne polyalkoxylates are neurotoxic, m tagenic, or clastogenic.

Follow ng subchronic exposure to rats, som gastrointestinal irritation w s observed, but no specific target organ toxicity or neurotoxicity w s seen. In subchronic studies in rats and/or dogs, the m st sensitive effects noted w re increased m rtality, clinical signs (salivation, w eezing, em sis, and/or soft feces), cataracts, cellular changes in the stom ch, and liver effects characterized by enzym induction, and pigm nt accum lation in Kupffer cells and bile canaliculi. There w s no increased susceptibility to the offspring of rats follow ng *in utero* exposure in tw prenatal developm ntal toxicity studies. H w ver, there is evidence of increased susceptibility in a reproductive screening study in rats.

Specific inform tion on the studies received and the nature of the adverse effects caused by alkyl am ne polyalkoxylates as w ll as the no-observed-adverse-effect-level (N L) and the low st-observed-adverse-effect-level (LO L) from the toxicity studies can be found at *http://w regulations.gov* in docum nt *A kyl A ne Polyalkoxylates (JITF CST 4 Inert Ingredients), Hum n Health Risk A sessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When U ed as Inert Ingredients in Pesticide Form lations*, at pp 10-17 in docket ID num er EPA H O P–2008–0738.

B. Toxicological Endpoints

For hazards that have a threshold below w ich there is no appreciable risk, a toxicological point of departure (PO) is identified as the basis for derivation of reference values for risk assessm nt. The PO m y be defined as the highest dose at w ich no adverse effects are observed (the N L) in the toxicology study identified as appropriate for use in risk assessm nt. H w ver, if a N L cannot be determ ned, the low st dose at w ich adverse effects of concern are identified (the LO L) or a Benchm rk Dose (BM) approach is som tim s used for risk assessm nt. U certainty/safety factors (U s) are used in conjunction w th the PO to take into account uncertainties inherent in the extrapolation from laboratory anim l data to hum ns and in the variations in sensitivity am ng m m ers of the hum n population as w ll as other unknow s. Safety is assessed for acute and chronic dietary risks by com aring aggregate food and w ter exposure to the pesticide to the acute population adjusted dose (aPA) and chronic population adjusted dose (cPA). The aPA and cPA are calculated by dividing the PO by all applicable U s. A gregate short-, interm diate-, and chronic-term risks are evaluated by com aring food, w ter, and residential exposure to the PO to ensure that the m rgin of exposure (M) called for by the product of all applicable U s is not exceeded. This latter value is referred to as the Level of Concern (LO).

For non-threshold risks, the A ency assum s that any am unt of exposure w ll lead to som degree of risk. Thus, the A ency estim tes risk in term of the probability of an occurrence of the adverse effect greater than that expected in a lifetim . For m re inform tion on the general principles EPA uses in risk characterization and a com lete description of the risk assessm nt process, see *http://w epa.gov/pesticides/factsheets/riskassess.htm*

A sum ry of the toxicological endpoints for alkyl am ne polyalkoxylates used for hum n risk assessm nt is show in the follow ng Table.

TABLE—SUM RY TO ICO O CAL DO ES ND ENDPO NTS O ALKYL AM NE PO YALKO YLATES O USE N HUM N RISK ASSESSM NT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LO for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)	NO EL = 72 m lligram /kilogram /day (m /kg/day) UF_A = 10x UF_H = 10x FQ A SF = 1x	Acute RfD = 0.72 m /kg/day aPAD = 0.72 m /kg/day	90-Day Oral Toxicity Study in Rats LO EL = 216 m /kg/day based on mortality (2 deaths after 2 exposures; gestation day (GD) 2), with a total of 6/25 deaths during GD 6-15.
Chronic dietary (all populations)	NO EL 15 m /kg/day UF_A = 10x UF_H = 10x FQ A SF = 1x	Chronic RfD = 0.15 m /kg/day cPAD = 0.15 m /kg/day	90-Day Oral (Gavage) Toxicity Study in Rats LO EL = 30 m /kg/day based on increased mortality (2 deaths (days 36, 78)), salivation, and posterior subcapsular cataracts in males as well as wheezing, and macro- and m croscopic changes in the nonglandular stomach of both sexes.

TABLE—SUM RY TO ICO O CAL DO ES ND ENDPO NTS O ALKYL AM NE PO YALKO YLATES O USE N HUM N RISK ASSESSM NT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LO for Risk Assessment	Study and Toxicological Effects
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months)	NO EL= 15 m /kg/day UF_A = 10x UF_H = 10x FQ A SF = 1x	LO for M = 100	90–Day Oral (Gavage) Toxicity Study in Rats LO EL = 30 m /kg/day based on increased mortality (2 deaths (days 36, 78)), salivation, and posterior subcapsular cataracts in males as well as wheezing, and macro- and m croscopic changes in the nonglandular stomach of both sexes.
Dermal and Inhalation (all durations)	Oral study NO EL = 15 m / kg/day (dermal absorption rate = 5% (inhalation absorption rate = 100% UF_A = 10x UF_H = 10x FQ A SF = 1x	LO for M = 100	90–Day Oral (Gavage) Toxicity Study in Rats LO EL = 30 m /kg/day based on increased mortality (2 deaths (days 36, 78)), salivation, and posterior subcapsular cataracts in males as well as wheezing, and macro- and m croscopic changes in the nonglandular stomach of both sexes.
Cancer (oral, dermal, inhalation)	Classification: No animal toxicity data available for an assessment; Based on SAR analysis, alkyl am ne polyalkoxylates are not expected to be carcinogenic.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among mem ers of the human population (intraspecies). RfD = reference dose.

C. Exposure A sessm nt

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to alkyl am ne polyalkoxylates, EPA considered exposure under the petitioned-for exem tions from the requirem nt of a tolerance. EPA assessed dietary exposures from alkyl am ne polyalkoxylates in food as follow :

i. *A ute and chronic exposure.* In conducting the acute and chronic dietary exposure assessm nts, EPA used food consum tion inform tion from the U ited States Departm nt of A riculture (U DA 1994–1996 and 1998 N tionw de Continuing Surveys of Food Intake by Individuals (CSFII). A to residue levels in food, no residue data w re subm tted for the alkyl am ne polyalkoxylates. In the absence of specific residue data, EPA has developed an approach w ich uses surrogate inform tion to derive upper bound exposure estim tes for the subject inert ingredients. U per bound exposure estim tes are based on the highest tolerance for a given com dity from a list of high-use insecticides, herbicides, and fungicides. A com lete description of the dietary exposure and risk assessm nt can be found at *http://w regulations.gov* in *A kyl A nes Polyalkoxylates (Cluster 4): A ute and Chronic A gregate (Food and Drinking Water) Dietary Exposure and Risk A sessm nts for the Inerts* in docket ID num er EPA H O P–2008–0738.

In the assessm nt, the A ency assum d that the residue level of the inert ingredient w uld be no higher than the highest tolerance for a given com dity. Im licit in this assum tion is that there w uld be sim lar rates of degradation (if any) betw en the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances w uld be no higher than the concentration of the active ingredient.

The A ency believes the assum tions used to estim te dietary exposures lead to an extrem ly conservative assessm nt of dietary risk due to a series of com ounded conservatism . First, assum ng that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient w ll overstate exposure. The concentrations of active ingredient in agricultural products is generally at least 50 percent of the product and often can be m ch higher. Further, pesticide products rarely have a single inert ingredient; rather, there is generally a com ination of different inert ingredients used w ich additionally reduces the concentration of any single inert ingredient in the pesticide product relative to that of the active ingredient. In the case of alkyl am ne polyalkoxylates, EPA m de a specific adjustm nt to the dietary exposure assessm nt to account for the use lim tations of the am unt of alkyl am ne polyalkoxylates that m y be in form lations (no m re than 25 percent in herbicides and no m re than 10 percent in fungicides and insecticides) and assum d the alkyl am ne polyalkoxylates to be present at the m xim m lim tations rather than at equal quantities w th the active ingredient. This rem ins a very conservative assum tion because surfactants are generally used at levels far below these percentages. For exam le, EPA exam ned several of the pesticide products associated w th the tolerance/com dity com ination w ich are the driver of the risk assessm nt and found that these products did not contain surfactants at levels greater than 2.25 percent and that none of the surfactants w re alkyl am ne polyalkoxylates.

Second, the conservatism of this m thodology is com ounded by EPA's decision to assum that, for each com dity, the active ingredient w ich w ll serve as a guide to the potential level of inert ingredient residues is the active ingredient w th the highest tolerance level. This assum tion overstates residue values because it w uld be highly unlikely, given the high num er of inert ingredients, that a single inert ingredient or class of ingredients w uld be present at the level of the active ingredient in the highest tolerance for every com dity.

Finally, a third com ounding conservatism is EPA's assum tion that all foods contain the inert ingredient at the highest tolerance level. In other w rds, EPA assum d 100 percent of all foods are treated w th the inert ingredient at the rate and m nner necessary to produce the highest residue legally possible for an active ingredient. In sum EPA chose a very conservative m thod for estim ting w at level of inert residue could be on food, then used this m thodology to choose the highest possible residue that could be found on food and assum d that all food contained this residue. N consideration

w s given to potential degradation betw en harvest and consum tion even though m nitoring data show that tolerance level residues are typically one to tw orders of m gnitude higher than actual residues in food w en distributed in com rce.

A cordingly, although sufficient inform tion to quantify actual residue levels in food is not available, the com ounding of these conservative assum tions w ll lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestim tes exposure in the absence of residue data.

ii. *Cancer.* The A ency used a qualitative structure activity relationship (SA) database, DEREK11, to determ ne if there w re structural alerts for potential carcinogenicity of both a representative alkyl am ne polyalkoxylate, as w ll as a possible m tabolite/degradate of alkyl am ne polyalkoxylate that had been extensively dealkylated, w th the am ne group intact. N structural alerts for carcinogenicity w re identified in either case. A kyl am ne polyalkoxylates are not expected to be carcinogenic. Therefore a cancer dietary exposure assessm nt is not necessary to assess cancer risk.

iii. *A ticipated residue and percent crop treated (PCT) inform tion.* EPA did not use anticipated residue and/or PCT inform tion in the dietary assessm nt for alkyl am ne polyalkoxylates. Tolerance level residues and/or 100 percent CT w re assum d for all food com dities.

2. *Dietary exposure from drinking w ter.* The A ency used screening level w ter exposure m dels in the dietary exposure analysis and risk assessm nt for alkyl am ne polyalkoxylates in drinking w ter. These sim lation m dels take into account data on the physical, chem cal, and fate/transport characteristics of alkyl am ne polyalkoxylates. Further inform tion regarding EPA drinking w ter m dels used in pesticide exposure assessm nt can be found at *http://w epa.gov/oppefed1/m dels/w ter/index.htm*

A screening level drinking w ter analysis, based on the Pesticide Root Zone M del/Exposure A alysis M deling System (PRZM EXA) w s perform d to calculate the estim ted drinking w ter concentrations (EDWCs) of alkyl am ne polyalkoxylates. M deling runs on four surrogate inert ingredients using a range of physical chem cal properties that w uld bracket those of the alkyl am ne polyalkoxylates w re conducted. M deled acute drinking w ter values ranged from 0.001 parts per billion (ppb) to 41 ppb. M deled chronic drinking w ter values ranged from 0.0002 ppb to 19 ppb. Further details of this drinking w ter analysis can be found at *http://w regulations.gov* in docum nt *A kyl A ne Polyalkoxylates (JITF CST 4 Inert Ingredients), Hum n Health Risk A sessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When U ed as Inert Ingredients in Pesticide Form lations,* at pp 18 and 70–72 in docket ID num er EPA H O P–2008–0738.

For the purpose of the screening level dietary risk assessm nt to support this request for an exem tion from the requirem nt of a tolerance for alkyl am ne polyalkoxylates, a conservative drinking w ter concentration value of 100 ppb based on screening level m deling w s used to assess the contribution to drinking w ter for both the acute and chronic dietary risk assessm nts. These values w re directly entered into the dietary exposure m del.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this docum nt to refer to non-occupational, non-dietary exposure (e.g., for law and garden pest control, indoor pest control, term ticides, and flea and tick control on pets). A kyl am ne polyalkoxylates are not used as inert ingredients in pesticide products that are registered for specific uses that could result in indoor residential exposures but m y have uses as inert ingredients in pesticide products that m y result in outdoor residential exposures.

A screening level residential exposure and risk assessm nt w s com leted for products containing alkyl am ne polyalkoxylates as inert ingredients. In this assessm nt, representative scenarios, based on end-use product application m thods and labeled application rates, w re selected. For each of the use scenarios, the A ency assessed residential handler (applicator) inhalation and derm l exposure for outdoor scenarios w th high exposure potential (i.e., exposure scenarios w th high end unit exposure values) to serve as a screening assessm nt for all potential residential pesticides containing alkyl am ne polyalkoxylates. Sim larly, residential postapplication derm l and oral exposure assessm nts w re also perform d utilizing high end outdoor exposure scenarios. Further details of this residential exposure and risk analysis can be found at *http://w regulations.gov* in docum nt *A kyl A ne Polyalkoxylates (JITF CST 4 Inert Ingredients), Hum n Health Risk A sessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When U ed as Inert Ingredients in Pesticide Form lations*, at pp 22–26 and 74–80 in docket ID num er EPA H O P–2008–0738.

4. *Cum lative effects from substances w th a com n m chanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, w en considering w ether to establish, m dify, or revoke a tolerance, the A ency consider ''available inform tion'' concerning the cum lative effects of a particular pesticide's residues and ''other substances that have a com n m chanism of toxicity.''

EPA has not found alkyl am ne polyalkoxylates to share a com n m chanism of toxicity w th any other substances, and alkyl am ne polyalkoxylates do not appear to produce a toxic m tabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assum d that alkyl am ne polyalkoxylates do not have a com n m chanism of toxicity w th other substances. For inform tion regarding EPA's efforts to determ ne w ich chem cals have a com n m chanism of toxicity and to evaluate the cum lative effects of such chem cals, see EPA's w bsite at *http://w epa.gov/pesticides/cum lative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) m rgin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the com leteness of the database on toxicity and exposure unless EPA determ nes based on reliable data that a different m rgin of safety w ll be safe for infants and children. This additional m rgin of safety is com nly referred to as the FQ A safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor w en reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicity database consists of a rat developm ntal toxicity study on an alkyl am ne polyalkoxylate and a rat reproduction study on tw different alkyl am ne polyalkoxylates w ich covers the range of carbon chain lengths and polyalkoxylation w thin the group. N quantitative or qualitative increased susceptibility w s dem nstrated in the fetuses in the prenatal developm ntal toxicity study in rats follow ng *in utero* exposure. There w s som evidence of increased susceptibility in the rat reproductive toxicity study (w ere the offspring N L of 300 ppm (12–14

m /kg/day) w s low r than the parental N L of 1,000 ppm (41–48.6 m /kg/day). There are no neurotoxicity studies available for the alkyl am ne polyalkoxylates; how ver, there is no indication of neurotoxicity in the available toxicity studies.

Based on the evidence of increased susceptibility in the offspring relative to the parents in the rat reproduction study a Degree of Concern analysis w s perform d. The purpose of the Degree of Concern analysis w s (1) to determ ne the level of concern for the effects observed w en considered in the context of all available toxicity data; and (2) identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessm nt.

There w s no increased susceptibility to the offspring of rats follow ng *in utero* exposure to alkyl am ne polyalkoxylates in the prenatal developm nt toxicity study. H w ver, there w s evidence of increased susceptibility in the reproduction toxicity studies in rats. O fspring effects include litter loss, increased m an num er of unaccounted–for im lantation sites and decreased m an num er of pups born, live litter size and postnatal survival from birth to LD 4 (F1) at 1,000 ppm for one alkyl am ne polyalkoxylate hom logue (41–48.6 m /kg/day) and at 2,000 ppm (134–148 m /kg/day) for a second hom logue. H w ver, the rat reproduction study identified a N L of 300 ppm for both hom logues (12–14 m /kg/day and 23–26 m /kg/day, respectively) for offspring effects, and the selected point of departure for the dietary, derm l and inhalation risk assessm nts is protective of these offspring effects, thus there are no residual concerns.

3. *Conclusion.* EPA has determ ned that reliable data show the safety of infants and children w uld be adequately protected if the FQ A SF w re reduced to 1X. That decision is based on the follow ng findings:

i. The toxicity database for alkyl am ne polyalkoxylates is considered adequate for assessing the risks to infants and children (the available studies are described in U it IV.4.D.2. above).

ii. There is no indication that alkyl am ne polyalkoxylates are neurotoxic chem cals and thus there is no need for a developm ntal neurotoxicity study or additional U s to account for neurotoxicity.

iii. There is no evidence that alkyl am ne polyalkoxylates result in increased susceptibility in *in utero* rats in prenatal developm ntal studies. Increased susceptibility of young rats in the 2–generation reproduction study w s seen, how ver the selected point of departure for the dietary, derm l and inhalation risk assessm nts is protective of these offspring effects, thus there are no residual concerns.

iv. N chronic studies on alkyl am ne polyalkoxylates are available, how ver, there is no need to add additional U s to account for an incom lete toxicity database because the adverse effects observed in the available toxicity studies do not seem to increase in severity over tim (4 w eks to 13 w eks). Based on the lack of progression of severity of effects w th tim along w th the considerable sim larities of effects across the species tested and the observation that the vast m jority of the effects observed are related to local irritation and corrosive effects, EPA concludes that an additional U for extrapolation from subchronic toxicity study to a chronic exposure scenario is not needed.

v. There are no residual uncertainties identified in the exposure databases. The food and drinking w ter assessm nt is not likely to underestim te exposure to any subpopulation, including those com rised of infants and children. The food exposure assessm nts are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100 percent crop treated is assum d for all crops. EPA also m de conservative (protective) assum tions in the ground and surface w ter m deling used to assess exposure to alkyl am ne polyalkoxylates in drinking w ter. EPA used sim larly conservative assum tions to assess postapplication exposure of children as w ll as incidental oral exposure of toddlers. These assessm nts w ll not underestim te the exposure and risks posed by alkyl am ne polyalkoxylates.

E. A gregate Risks and Determ nation of Safety

EPA determ nes w ether acute and chronic pesticide exposures are safe by com aring aggregate exposure estim tes to the aPA and cPA . The aPA and cPA represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPA and cPA by dividing the PO by all applicable U s. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estim ted aggregate exposure. Short–, interm diate–, and chronic–term risks are evaluated by com aring the estim ted aggregate food, w ter, and residential exposure to the PO to ensure that the M called for by the product of all applicable U s is not exceeded.

In conducting this aggregate risk assessm nt, the A ency has incorporated the petitioner's requested use lim tations of alkyl am ne polyalkoxylates as inert ingredients in pesticide product form lations into its exposure assessm nt. Specifically the petition includes a use lim tation of alkyl am ne polyalkoxylates at not m re than 10 percent by w ight in fungicide and insecticide form lations and at no m re than 25 percent in herbicide form lations.

1. *A ute risk.* A acute aggregate risk assessm nt takes into account exposure estim tes from acute dietary consum tion of food and drinking w ter. U ing the exposure assum tions discussed in this unit for acute exposure, and the use lim tations of not m re than 10 percent by w ight in fungicide and insecticide form lations and at no m re than 25 percent in herbicide form lations, the acute dietary exposure from food and w ter to alkyl am ne polyalkoxylates at the 95th percentile for food and drinking w ter is 16 percent of the aPA for the U S. population and 44 percent of the aPA for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* A chronic aggregate risk assessm nt takes into account exposure estim tes from chronic dietary consum tion of food and drinking w ter U ing the exposure assum tions discussed in this unit for chronic exposure, and the use lim tations of not m re than 10 percent by w ight in fungicide and insecticide form lations and at no m re than 25 percent in herbicide form lations, the chronic dietary exposure from food and w ter to alkyl am ne polyalkoxylates is 27 percent of the cPA for the U S. population and 85 percent of the cPA for children 1 to 2 years old, the m st highly exposed population subgroup.

3. *Short–term risk.* Short–term aggregate exposure takes into account short–term residential exposure plus chronic exposure to food and w ter (considered to be a background exposure level).

A kyl am ne polyalkoxylates are used as inert ingredients in pesticide products that are currently registered for uses that could result in short–term residential exposure and the A ency has determ ned that it is appropriate to aggregate chronic exposure through food and w ter w th short–term residential exposures to alkyl am ne polyalkoxylates.

U ing the exposure assum tions described in this unit for short–term

exposures, EPA has concluded the com ined short–term food, w ter, and residential exposures aggregated result in aggregate M s of 156 and 172, for adult m les and fem les respectively, for a com ined high end derm l and inhalation handler exposure w th a high end post application derm l exposure and an aggregate M of 90 for children for a com ined turf derm l exposure w th hand-to-m uth exposure. While the M for short-term aggregate exposure for children is slightly below 100, EPA does not consider this M to represent a risk of concern for the follow ng reasons.

• The hazard assessm nt for the alkyl am ne polyalkoxylates is conservative. The PO s used to calculate aggregate risks for alkyl am ne polyalkoxylates w re based on the m st toxic surrogate chem cal. The alkyl am ne polyalkoxylates are actually a m xture of com ounds, so it is likely that the PO is a conservative assessm nt of toxicity.

• The A ency traditionally considers a level of concern (LO) for these risk assessm nts to be for an M of 100 based on the standard 10x inter- and 10x intraspecies extrapolation safety factors. H w ver, for alkyl am ne polyalkoxylates, the prim ry toxic effect seen is related to the surfactants' inherent function to disrupt cell m m ranes resulting in irritating properties to tissues. Given that a significant difference betw en species for this type of effect is not expected, an LO low r than an M of 100 m y be appropriate for the non-dietary risk assessm nts.

• The dietary (food and w ter) portion of the aggregate risk assessm nt is a driver in this aggregate assessm nt and is considered to be highly conservative.

• The highest tolerance level from the surrogate pesticides for every food is used adjusted by the lim tation in form lation for alkyl am ne polyalkoxylates specified in the exem tion. Estim ting alkyl am ne polyalkoxylates exposure based on the assum tion that alkyl am ne polyalkoxylates w ll be present at the m xim m perm tted am unt in the pesticide products producing the highest possible residue in food is very conservative. EPA exam ned several of the pesticide products associated w th the tolerance/com dity com ination w ich are the driver of the risk assessm nt and found that these products contained betw en 1 and 2.25 percent surfactant, none of w ich w s alkyl am ne polyalkoxylates.

•100 percent crop treated is assum d for all crops (every food eaten by a person each day has tolerance-level residues).

•M ny of these high tolerances are based on very short pre-harvest intervals w ere there is little tim for degradation.

•N consideration w s given to potential degradation betw en harvest and consum tion (use of tolerance level residues w ich are typically one to tw orders of m gnitude higher than actual residues found in m nitoring data).

•N consideration w s given to potential reduction in residues from w shing or cooking.

• The residential portion of the assessm nt is based on high-end application rates and assum s a derm l absorption of 5 percent w ich is a conservative, health protective value.

• Finally, the aggregate assessm nt assum s that a child w uld receive a high-end dietary exposure w th high-end derm l and hand-to-m uth exposures concurrently.

4. *Interm diate-term risk.* Interm diate-term aggregate exposure takes into account interm diate-term residential exposure plus chronic exposure to food and w ter (considered to be a background exposure level).

A kyl am ne polyalkoxylates are used as inert ingredients in pesticide products that are currently registered for uses that could result in interm diate-term residential exposure and the A ency has determ ned that it is appropriate to aggregate chronic exposure through food and w ter w th interm diate-term residential exposures to alkyl am ne polyalkoxylates.

U ing the exposure assum tions described in this unit for short-term exposures, EPA has concluded the com ined short-term food, w ter, and residential exposures aggregated result in aggregate M s of 156 and 172, for adult m les and fem les respectively, for a com ined high end derm l and inhalation handler exposure w th a high end post application derm l exposure and an M of 102 for children for a com ined high end derm l exposure w th hand-to-m uth exposure.

5. *Determ nation of safety.* Based on these risk assessm nts, EPA concludes that there is a reasonable certainty that no harm w ll result to the general population, or to infants and children from aggregate exposure to residues of alkyl am ne polyalkoxylates.

IV. Other Considerations

A A alytical Enforcem nt M thodology

A analytical m thod is not required for enforcem nt purposes since the A ency is establishing an exem tion from the requirem nt of a tolerance w thout any num rical lim tation.

B. International Residue Lim ts

The A ency is not aw re of any country requiring a tolerance for alkyl am ne polyalkoxylates nor have any CO EX M xim m Residue Levels been established for any food crops at this tim .

V. Conclusion

Therefore, an exem tion from the requirem nt of a tolerance is established for residues of alkyl am ne polyalkoxylates w en used as an inert ingredient in pesticide form lations applied to grow ng crops or to anim ls.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition subm tted to the A ency. The O fice of M nagem nt and Budget (O) has exem ted these types of actions from review under Executive O der 12866, entitled *Regulatory Planning and Review* (58 FR 51735, O tober 4, 1993). Because this final rule has been exem ted from review under Executive O der 12866, this final rule is not subject to Executive O der 13211, entitled *A tions Concerning Regulations That Significantly A fect Energy Supply, Distribution, or U e* (66 FR 28355, M y 22, 2001) or Executive O der 13045, entitled *Protection of Children from Environm ntal Health Risks and Safety Risks* (62 FR 19885, A ril 23, 1997). This final rule does not contain any inform tion collections subject to O approval under the Paperw rk Reduction A t (PRA , 44 U S.C. 3501 *et seq.*, nor does it require any special considerations under Executive O der 12898, entitled *Federal A tions to A dress Environm ntal Justice in M nority Populations and Low-Incom Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exem tions 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 requirem nts of the Regulatory Flexibility A t (RFA (5 U S.C. 601 *et seq.*) do not apply.

This final rule directly regulates grow rs, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of pow r and responsibilities established by Congress in the preem tion provisions of section 408(n)(4) of FFDCA A such, the A ency has determ ned that this action w ll not have a substantial direct effect on States or tribal governm nts, on the relationship betw en the national

governm nt and the States or tribal governm nts, or on the distribution of pow r and responsibilities am ng the various levels of governm nt or betw en the Federal Governm nt and Indian tribes. Thus, the A ency has determ ned that Executive O der 13132, entitled *Federalism* (64 FR 43255, A gust 10, 1999) and Executive O der 13175, entitled *Consultation and Coordination w th Indian Tribal Governm nts* (65 FR 67249, N vem er 9, 2000) do not apply to this final rule. In addition, this final rule does not im ose any enforceable duty or contain any unfunded m ndate as described under Title II of the U funded M ndates Reform A t of 1995 (U A (Public Law 104–4).

This action does not involve any technical standards that w uld require A ency consideration of voluntary consensus standards pursuant to section 12(d) of the N tional Technology Transfer and A vancem nt A t of 1995 (N TA , Public Law 104–113, section 12(d) (15 U S.C. 272 note).

VII. Congressional Review A t

The Congressional Review A t, 5 U S.C. 801 *et seq.*, generally provides that before a rule m y take effect, the agency prom lgating the rule m st subm t a rule report to each H use of the Congress and to the Com troller General of the U ited States. EPA w ll subm t a report containing this rule and other required inform tion to the U S. Senate, the U S. H use of Representatives, and the Com troller General of the U ited States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''m jor rule'' as defined by 5 U S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environm ntal protection, A m nistrative practice and procedure, A ricultural com dities, Pesticides and pests, Reporting and recordkeeping requirem nts.

Dated: June 2, 2009.

Lois Rossi,

Director, Registration Division, O fice of Pesticide Program .

■ Therefore, 40 CFR chapter I is am nded as follow :

PART 180—[AM NDED]

■ 1. The authority citation for part 180 continues to read as follow :

A thority: 21 U S.C. 321(q), 346a and 371.

■ 2. In § 180.920, the table is am nded by adding alphabetically the new inert ingredients to read as follow :

§ 180.920 nert ingredients used pre-harvest; exem tions from the requirem nt of a tolerance.

* * * * *

Inert Ingredients	Lim ts	Uses
*		
N,N-Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl) C_8-C_{18} saturated nd nsaturated lkylam nes; he poly(oxy-1,2-ethanediyl) content is 2–60 moles (CAS Reg. Nos. 10213–78–2, 25307–17–9, 26635–92–7, 26635–93–8, 288259–52–9, 8253–49–9, 1790–82–7, 1791–14–8, 1791–24–0, 61791–26–2, 1791–31–9, 1791–44–4, 8155–33–9, 68155–39–5, 68155–40–8,70955–14–5, 73246–96–5)	Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations	Surfactants, elated djuvants f surfactants
*		
N,N–Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) C_8-C_{18} saturated nd nsaturated alkylam nes; he poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) content is 2–60 moles (CAS Reg. Nos. 68213–26–3, 68153–97–9, 75601–76–2)	Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations	Surfactants, elated djuvants f surfactants
*		

■ 3. In § 180.930, the table is am nded by adding alphabetically new entries of inert ingredients to read as follow :

§ 180.930 nert ingredients applied to anim ls; exem tions from the requirem nt of a tolerance.

* * * * *

Inert Ingredients	Lim ts	Uses
*		
N,N-Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl) C_8-C_{18} saturated nd nsaturated lkylam nes; he poly(oxy-1,2-ethanediyl) content is 2–60 moles (CAS Reg. Nos. 10213–78–2, 25307–17–9, 26635–92–7, 26635–93–8, 288259–52–9, 8253–49–9, 1790–82–7, 1791–14–8, 1791–24–0, 61791–26–2, 1791–31–9, 1791–44–4, 8155–33–9, 68155–39–5, 68155–40–8,70955–14–5, 73246–96–5)	Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations	Surfactants, elated djuvants f surfactants
*		
N,N-Bis-α-ethyl-ω-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) C_8-C_{18} saturated nd nsaturated alkylam nes; he poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) content is 2–60 moles (CAS Reg. Nos. 68213–26–3, 68153–97–9, 75601–76–2)	Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations	Surfactants, elated djuvants f surfactants
*		

[FR Doc. E9–14113 Filed 6–16–09; 8:45 am
BILLING CO E 6560–50–S

DEPARTM NT O HO LAND SECURITY

Federal Em rgency M nagem nt Agency

44 CFR Part 64

[Docket ID FEM –2008–0020; Internal Agency Docket No. FEM –8079]

Suspension of Com nity Eligibility

AG NCY: Federal Em rgency M nagem nt A ency, DH .

ACTIO : Final rule.

SUM RY: This rule identifies com nities, w ere the sale of flood insurance has been authorized under the N tional Flood Insurance Program (N IP), that are scheduled for suspension on the effective dates listed w thin this rule because of noncom liance w th the floodplain m nagem nt requirem nts of the program If the Federal Em rgency M nagem nt A ency (FEM receives docum ntation that the com nity has adopted the required floodplain m nagem nt m asures prior to the effective suspension date given in this rule, the suspension w ll not occur and a notice of this w ll be provided by publication in the **Federal Register** on a subsequent date.

DATES: *Effective Dates:* The effective date of each com nity's scheduled suspension is the third date (''Susp.'') listed in the third colum of the follow ng tables.

FO URTHER NFO M TIO O TACT: If you w nt to determ ne w ether a particular com nity w s suspended on the suspension date or for further inform tion, contact David Stearrett, M tigation Directorate, Federal Em rgency M nagem nt A ency, 500 C Street, SW., Washington, DC 20472, (202) 646–2953.

SUPPLEM NTARY NFO M TIO : The N IP enables property ow ers to purchase flood insurance w ich is generally not otherw se available. In return, com nities agree to adopt and adm nister local floodplain m nagem nt aim d at protecting lives and new construction from future flooding. Section 1315 of the N tional Flood Insurance A t of 1968, as am nded, 42 U S.C. 4022, prohibits flood insurance coverage as authorized under the N IP, 42 U S.C. 4001 *et seq.;* unless an appropriate public body adopts adequate floodplain m nagem nt m asures w th effective enforcem nt m asures. The com nities listed in this docum nt no longer m et that statutory requirem nt for com liance w th program regulations, 44 CFR part 59. A cordingly, the com nities w ll be suspended on the effective date in the third colum . A of that date, flood insurance w ll no longer be available in the com nity. H w ver, som of these com nities m y adopt and subm t the required docum ntation of legally enforceable floodplain m nagem nt m asures after this rule is published but prior to the actual suspension date. These com nities w ll not be suspended and w ll continue their eligibility for the sale of insurance. A notice w thdraw ng the suspension of the com nities w ll be published in the **Federal Register.**

In addition, FEM has identified the Special Flood H zard A eas (SFH) in these com nities by publishing a Flood Insurance Rate M p (FIRM . The date of the FIRM if one has been published, is indicated in the fourth colum of the table. N direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Em rgency A sistance A t not in connection w th a flood) m y legally be provided for construction or acquisition of buildings in identified SFH for com nities not participating in the N IP and identified for m re than a year, on FEM 's initial flood insurance m p of the com nity as having flood-prone areas (section 202(a) of the Flood Disaster Protection A t of 1973, 42 U S.C. 4106(a), as am nded). This prohibition against certain types of Federal assistance becom s effective for the com nities listed on the date show in the last colum . The A m nistrator finds that notice and public com nt under 5 U S.C. 553(b) are im racticable and unnecessary because com nities listed in this final rule have been adequately notified.

Each com nity receives 6-m nth, 90-day, and 30-day notification letters addressed to the Chief Executive O ficer stating that the com nity w ll be suspended unless the required floodplain m nagem nt m asures are m t prior to the effective suspension date. Since these notifications w re m de, this final rule m y take effect w thin less than 30 days.

National Environm ntal Policy A t. This rule is categorically excluded from the requirem nts of 44 CFR part 10, Environm ntal Considerations. N environm ntal im act assessm nt has been prepared.

Regulatory Flexibility A t. The A m nistrator has determ ned that this rule is exem t from the requirem nts of the Regulatory Flexibility A t because the N tional Flood Insurance A t of 1968, as am nded, 42 U S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain m nagem nt m asures w th effective enforcem nt m asures. The com nities listed no longer com ly w th the statutory requirem nts, and after the effective date, flood insurance w ll no longer be available in the com nities unless rem dial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive O der 12866 of Septem er 30, 1993, Regulatory Planning and Review 58 FR 51735.

Executive O der 13132, Federalism This rule involves no policies that have federalism im lications under Executive O der 13132.

Executive O der 12988, Civil Justice Reform This rule m ets the applicable standards of Executive O der 12988.

Paperw rk Reduction A t. This rule does not involve any collection of inform tion for purposes of the Paperw rk Reduction A t, 44 U S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

■ A cordingly, 44 CFR part 64 is am nded as follow :

PART 64—[AM NDED]

■ 1. The authority citation for part 64 continues to read as follow :

A thority: 42 U S.C. 4001 *et seq.;* Reorganization Plan N . 3 of 1978, 3 CFR, 1978 Com .; p. 329; E.O 12127, 44 FR 19367, 3 CFR, 1979 Com .; p. 376.

§ 64.6 Am nded]

■ 2. The tables published under the authority of § 64.6 are am nded as follow :

Exhibit 28

[FR Doc. E9–17945 Filed 7–28–09; 8:45 am
BILLING CO E 6560–50–S

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 180

[EPA–HQ O P–2009–0131; FRL–8424–6]

Alkyl Alcohol Alkoxylate Phosphate and Sulfate Derivatives; Exem tion From the Requirem nt of a Tolerance

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Final rule.

SUM RY: This regulation establishes exem tions from the requirem nt of a tolerance for residues of alkyl alcohol alkoxylate phosphate derivatives w en used as inert ingredients in grow ng crops under 40 CFR 180.920 and for residues of alkyl alcohol alkoxylate sulfate derivatives w en used as inert ingredients in pesticide form lations applied to grow ng crops, raw agricultural com dities after harvest, and anim ls under 40 CFR 180.910 and 40 CFR 180.930. The Joint Inerts Task Force (JITF), Cluster Support Team N m er 2 (CST 2) subm tted a petition to EPA under the Federal Food, Drug, and Cosm tic A t (FFDCA , requesting an exem tion from the requirem nt of a tolerance. This regulation elim nates the need to establish a m xim m perm ssible level for residues of alkyl alcohol alkoxylate phosphate and sulfate derivatives.

DATES: This regulation is effective July 29, 2009. O jections and requests for hearings m st be received on or before Septem er 28, 2009, and m st be filed in accordance w th the instructions provided in 40 CFR part 178 (see also U it I.C. of the **SUPPLEM NTARY INFO M TIO).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) num er EPA H O P–2009–0131. A l docum nts in the docket are listed in the docket index available at *http://w regulations.gov*. A though listed in the index, som inform tion is not publicly available, e.g., Confidential Business Inform tion (CBI) or other inform tion w ose disclosure is restricted by statute. Certain other m terial, such as copyrighted m terial, is not placed on the Internet and w ll be publicly available only in hard copy form Publicly available docket m terials are available in the electronic docket at *http://w regulations.gov*, or, if only available in hard copy, at the O P Regulatory Public Docket in Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA The Docket Facility is open from 8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays. The Docket Facility telephone num er is (703) 305–5805.

FO URTHER NFO M TIO O TACT: Kerry Leifer, Registration Division (7505P), O fice of Pesticide Program , Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001; telephone num er: (703) 308–8811; e-m il address: *leifer.kerry @epa.gov*.

SUPPLEM NTARY NFO M TIO : I

I. G neral Inform tion

A Does this A tion A ply to M ?

You m y be potentially affected by this action if you are an agricultural producer, food m nufacturer, or pesticide m nufacturer. Potentially affected entities m y include, but are not lim ted to those engaged in the follow ng activities:

- rop production (N CS code 111).
- im l production (N CS code A 112).
- ood m nufacturing (N CS codeF 311).
- esticide m nufacturing (N CS P code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. O her types of entities not listed in this unit could also be affected. The N rth A rican Industrial Classification System (N CS) codes have been provided to assist you and others in determ ning w ether this action m ght apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FO URTHER INFO M TIO O TACT.**

B. H w Can I A cess Electronic Copies of this Docum nt?

In addition to accessing electronically available docum nts at *http://w regulations.gov*, you m y access this **Federal Register** docum nt electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://w epa.gov/fedrgstr*. You m y also access a frequently updated electronic version of EPA s tolerance regulations at 40 CFR part180 through the Governm nt Printing O fice's e-CFR cite at *http://w gpoaccess.gov/ecfr*. To access the O PTS H rm nized Guidelines referenced in this docum nt, go directly to the guidelines at *http://w epa.gov/opptsfrs/hom / guidelin.htm*

C. Can I File an O jection or H aring Request?

U der section 408(g) of FFDCA 21 U S.C. 346a, any person m y file an objection to any aspect of this regulation and m y also request a hearing on those objections. You m st file your objection or request a hearing on this regulation in accordance w th the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA you m st identify docket ID num er EPA H O P–2009–0131 in the subject line on the first page of your subm ssion. A l requests m st be in w iting, and m st be m iled or delivered to the H aring Clerk as required by 40 CFR part 178 on or before Septem er 28, 2009.

In addition to filing an objection or hearing request w th the H aring Clerk as described in 40 CFR part 178, please subm t a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES.** Inform tion not m rked confidential pursuant to 40 CFR part 2 m y be disclosed publicly by EPA w thout prior notice. Subm t this copy, identified by docket ID num er EPA H O P–2009–0131, by one of the follow ng m thods:

- *ederal eRulem king Portal*: *http://w regulations.gov*. Follow the on-line instructions for subm tting com nts.
- *il*: O fice of Pesticide Program *M* (O P) Regulatory Public Docket (7502P), Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001.
- *elivery*: O P Regulatory Public *D* Docket (7502P), Environm ntal Protection A ency, Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA Deliveries are only accepted during the Docket Facility's norm l hours of operation (8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays). Special arrangem nts should be m de for deliveries of boxed inform tion. The Docket Facility telephone num er is (703) 305–5805.

II. Background

In the **Federal Register** of A ril 15, 2009 (74 FR 17487) (FRL–8409–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA 21 U S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7533) by JITF, CST 2, c/o CropLife A rica, 1156 15th St., N , Suite 400, Washington, DC 20005, The petition requested that 40 CFR 180.910, 40 CFR 180.920, and 40 CFR 180.930 be am nded by establishing exem tions from the

requirem nt of a tolerance for residues of various alkyl alcohol alkoxylate phosphate and sulfate derivatives w en used as inert ingredients in pesticide form lations applied to raw agricultural com dities, grow ng crops, and anim ls. The petition specifically requested the establishm nt of an exem tion from the requirem nt of a tolerance under 40 CFR 180.920 for residues of α-alkyl (m nim m C_6 linear, branched, saturated and/or unsaturated)-ω-hydroxypolyoxyethylene polym r w th or w thout polyoxypropylene, m xture of di- and m nohydrogen phosphateesters and the corresponding am nium calcium m gnesium m noethanolam ne, potassium sodium and zinc salts of the phosphate esters; m nim m oxyethylene content is 2 m les; m nim m oxypropylene content is 0 m les (Chem cal A stract Service Registry num ers (CA N s.) 9046–01–9, 39464–66–9, 50643–20–4, 52019–36–0, 68071–35–2, 68458–48–0, 68585–36–4, 68815–11–2, 68908–64–5, 68511–37–5,68130–47–2, 42612–52–2, 58318–92–6, 60267–55–2, 68070–99–5, 68186–36–7, 68186–37–8, 68610–65–1, 68071–17–0, 936100–29–7, 936100–30–0, 73038–25–2, 78330–24–2, 154518–39–5, 317833–96–8, 108818–88–8, 873662–29–4, 61837–79–4, 68311–02–4, 68425–73–0, 37280–82–3, 68649–29–6, 67711–84–6, 68891–13–4); and the establishm nt of an exem tion from the requirem nt of a tolerance under 40 CFR 180.910 and 40 CFR 180.930 for residues of α-alkyl(C_6-C_{15})-ω-hydroxypoly(oxyethylene)sulfate, and its am nium calcium m gnesium potassium sodium and zinc salts, poly(oxyethylene) content averages 2–4 m les (CA N s. 9004–82–4, 68585–34–2, 68891–38–3, 9004–84–6, 13150–00–0, 26183–44–8, 68611–55–2, 68511–39–7, 3088–31–1, 9004–82–4, 25446–78–0, 32612–48–9, 50602–06–7, 62755–21–9, 68424–50–0, 73665–22–2). For ease of reading, the alkyl alcohol alkoxylate phosphate and sulfate derivatives are referred to throughout this docum nt as A Ds and A Ds respectively, and collectively as A SDs. That notice referenced a sum ry of the petition prepared by JITF, CST 2, the petitioner w ich is available to the public in the docket, *http://w regulations.gov*. There w re no com nts received in response to the notice of filing.

This petition, w ich also included a lim tation of the concentration of alkyl alcohol alkoxylate phosphate and sulfate derivatives to not exceed 30% by w ight of the pesticide form lation, w s subm tted in response to a final rule of A gust 9, 2006 (71 FR 45415) (FRL–8084–1) in w ich the A ency revoked, under FFDCA section 408(e)(1) the existing exem tions from the requirem nt of a tolerance for residues of certain inert ingredients because of insufficient data to m ke the determ nation of safety required by FFDCA section 408(b)(2). The expiration date for the tolerance exem tions subject to revocation w s A gust 9, 2008, w ich w s later extended to A gust 9, 2009, by a docum nt published in the **Federal Register** issue of A gust 4, 2008 (73 FR 45312) (FRL–8372–7) to allow for data to be subm tted to support the establishm nt of tolerance exem tions for these inert ingredients prior to the effective date of the tolerance exem tion revocation.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not lim ted to, the follow ng types of ingredients (except w en they have a pesticidal efficacy of their ow): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polym rs and fatty acids; carriers such as clay and diatom ceous earth; thickeners such as carrageenan and m dified cellulose; w tting, spreading, and dispersing agents; propellants in aerosol dispensers; m croencapsulating agents; and em lsifiers. The term ''inert'' is not intended to im ly nontoxicity; the ingredient m y or m y not be chem cally active. Generally, EPA has exem ted inert ingredients from the requirem nt of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessm nt and Determ nation of Safety

Section 408(b)(2)(A (i) of FFDCA allow EPA to establish an exem tion from the requirem nt of a tolerance (the legal lim t for a pesticide chem cal residue in or on a food) only if EPA determ nes that the tolerance is ''safe.'' Section 408(b)(2)(A (ii) of FFDCA defines ''safe'' to m an that ''there is a reasonable certainty that no harm w ll result from aggregate exposure to the pesticide chem cal residue, including all anticipated dietary exposures and all other exposures for w ich there is reliable inform tion.'' This includes exposure through drinking w ter and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chem cal residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm w ll result to infants and children from aggregate exposure to the pesticide chem cal residue. . . .''

EPA perform a num er of analyses to determ ne the risks from aggregate exposure to pesticide chem cal residues. First, EPA determ nes the toxicity of pesticide chem cals. Second, EPA exam nes exposure to the pesticide chem cal through food, drinking w ter, and through other exposures that occur as a result of the pesticide chem cal use in residential settings.

Consistent w th FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has review d the available scientific data and other relevant inform tion in support of this action. EPA has sufficient data to assess the hazards of and to m ke a determ nation on aggregate exposure for the petitioned-for exem tion from the requirem nt of a tolerance for residues of A SDs w en used as inert ingredients in pesticide form lations applied to grow ng crops, raw agricultural com dities and food-producing anim ls. EPA s assessm nt of exposures and risks associated w th establishing tolerances follow .

A Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, com leteness, and reliability as w ll as the relationship of the results of the studies to hum n risk. EPA has also considered available inform tion concerning the variability of the sensitivities of m jor identifiable subgroups of consum rs, including infants and children.

The A SDs are not acutely toxic by the oral and derm l routes of exposure under norm l use conditions; how ver, concentrated m terials are generally m derate to severe eye and skin irritants and m y be skin sensitizers. Follow ng subchronic exposure to rats, gastrointestinal irritation (increased incidences of hyperplasia, subm cosal edem , and ulceration) w s observed, but no specific target organ toxicity or neurotoxicity w s seen. N neurotoxicological effects w re detected in a functional observational battery or a m tor activity assessm nt. N reproductive effects w re noted in the database. There w s a qualitative increase in susceptibility to pups seen in a rat developm ntal/reproductive toxicity screening study; how ver, effects w re seen only in one study and w re in the presence of m ternal toxicity. Further, a clear no-observed-adverse-effect-level (N L) w s

established for the developm ntal effects and this N L is significantly higher than the toxicological points of departure selected for risk assessm nt. There are no carcinogenicity concerns based on structure activity m deling. Points of departure for chronic dietary, incidental oral, inhalation, and derm l exposure w re selected from a 2–generation reproduction and fertility effects study in rats. The endpoint w s decreased absolute and relative liver w ights and increased incidence in the num er of anim ls w th m nim l hepatocyte necrosis in m les.

Sufficient data w re provided on the chem cal identity of the A SDs; how ver, lim ted data are available on the m tabolism and environm ntal degradation of these com ounds. The A ency relied collectively on inform tion provided on the representative chem cal structures, the subm tted physicochem cal data, structure activity relationship (SA) inform tion, as w ll as inform tion on other surfactants and chem cals of sim lar size and functionality to determ ne the residues of concern for the A SDs. The A ency has concluded that since m tabolites and environm ntal degradates are not likely to be m re toxic than the parent com ounds, a risk assessm nt based on the parent com ounds is not likely to underestim te risk.

Specific inform tion on the studies received and the nature of the adverse effects caused by the A SDs as w ll as the N L and the low st-observed-adverse-effect-level (LO L) from the toxicity studies can be found at *http://w regulations.gov* in docum nt *A kyl A cohol A koxylate Phosphate and Sulfate Derivatives (A Ds and A SDs—JITF CST 2 Inert Ingredients). H m n H alth Risk A sessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When Used as Inert Ingredients in Pesticide*, pages 11–17 in docket ID num er EPA H O P–2009–0131.

B. Toxicological Endpoints

For hazards that have a threshold below w ich there is no appreciable risk, a toxicological point of departure (PO) is identified as the basis for derivation of reference values for risk assessm nt. The PO m y be defined as the highest dose at w ich no adverse effects are observed (the N L) in the toxicology study identified as appropriate for use in risk assessm nt. H w ver, if a N L cannot be determ ned, the low st dose at w ich adverse effects of concern are identified (the LO L) or a benchm rk dose (BM) approach is som tim s used for risk assessm nt. U certainty/safety factors (U s) are used in conjunction w th the PO to take into account uncertainties inherent in the extrapolation from laboratory anim l data to hum ns and in the variations in sensitivity am ng m m ers of the hum n population as w ll as other unknow s. Safety is assessed for acute and chronic dietary risks by com aring aggregate food and w ter exposure to the pesticide to the acute population adjusted dose (aPA) and chronic population adjusted dose (cPA). The aPA and cPA are calculated by dividing the PO by all applicable U s. A gregate short-, interm diate-, and chronic-term risks are evaluated by com aring food, w ter, and residential exposure to the PO to ensure that the m rgin of exposure (M) called for by the product of all applicable U s is not exceeded. This latter value is referred to as the level of concern (LO).

For non-threshold risks, the A ency assum s that any am unt of exposure w ll lead to som degree of risk. Thus, the A ency estim tes risk in term of the probability of an occurrence of the adverse effect greater than that expected in a lifetim . For m re inform tion on the general principles EPA uses in risk characterization and a com lete description of the risk assessm nt process, see *http://w epa.gov/pesticides/factsheets/riskassess.htm*

A sum ry of the toxicological endpoints for A SDs used for hum n risk assessm nt is show in Table 1 of this unit.

TABLE 1.—SUM ARY TOXICO O ICAL DO ES AND ENDPOINTS O AAAPSDS O USE IN HUMAN RISK ASSESSM NT

Exposure/Scenario	Point of Departure and Uncertainty/ Safety Factors	RfD, PAD, LO for Risk Assessm nt	Study and Toxicological Effects
Acute dietary (all populations)	No appropriate endpoint was identified for acute dietary assessm nt		
Chronic dietary (all populations)	NOAEL= 87 m llgram /kilogram /day (mg/kg/day) UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.87 mg/kg/day cPAD = 0.87 mg/kg/day	Reproduction/fertility effects in m le rats (M s-ter ecord Identification um er (M ID) 47060903)) LOAEL = 223 mg/kg/day based on a dose-related decrease in absolute and relative liver weight and an increased incidence in the num er f nim ls ith "m nim l" hepatocyte necrosis in m les in the high-dose group compared to control group
Incidental oral short-term (1 to 30 days) and interm diate-term (1 to 6 m nths)	NOAEL= 87 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LO for M = 100	eproduction/fertility effects in m le rats (M ID 47060903) LOAEL = 223 mg/kg/day based on a dose-related decrease in absolute and relative liver weight and an increased incidence in the num er f nim ls ith "m nim l" hepatocyte necrosis in m les in the high-dose group compared to control group

TABLE 1.—SUM ARY TOXICO O ICAL DO ES AND ENDPOINTS O AAAPSDs O USE IN HUMAN RISK ASSESSM NT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/ Safety Factors	RfD, PAD, LO for Risk Assessm nt	Study and Toxicological Effects
Derm l and inhalation (all durations)	O al study NOAEL = 87 mg/kg/day (derm l absorption rate = 5% (inhalation absorption rate = 100% UF_A = 10x UF_H = 10x FQPA SF = 1x	LO for M = 100	eproduction/fertility effects in m le rats (M ID 47060903) LOAEL = 223 mg/kg/day based on a dose-related decrease in absolute and relative liver weight and an increased incidence in the num er f nim ls ith "m nim l" hepatocyte necrosis in m les in the high-dose group compared to control group.
Cancer (oral, derm l, inhalation)	Classification: No anim l toxicity data available for an assessm nt; based on SAR analysis, AAAPSDs are not expected to be carcinogenic.		

UF_A = extrapolation from anim l to hum n (interspecies). UF_H = potential variation in sensitivity am ng m m ers of the hum n population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. M = m rgin of exposure. LO = level of concern.

C. Exposure A sessm nt

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to A SDs, EPA considered exposure under the petitioned-for exem tions from the requirem nt of a tolerance. EPA assessed dietary exposures from A SDs in food as follow :

i. *A ute and chronic exposure.* In conducting the acute and chronic dietary exposure assessm nts, EPA used food consum tion inform tion from the U ited States Departm nt of A riculture (U DA 1994–1996 and 1998 N tionw de Continuing Surveys of Food Intake by Individuals (CSFII). A to residue levels in food, no residue data w re subm tted for the A SDs. In the absence of specific residue data EPA has developed an approach w ich uses surrogate inform tion to derive upper bound exposure estim tes for the subject inert ingredients. U per bound exposure estim tes are based on the highest tolerance for a given com dity from a list of high-use insecticides, herbicides, and fungicides. A com lete description of the dietary exposure and risk assessm nt can be found at *http:// w regulations.gov* in *A kyl A nes Polyalkoxylates (Cluster 4): A ute and Chronic A gregate (Food and Drinking Water) Dietary Exposure and Risk A sessm nts for the Inerts* in docket ID num er EPA H O P–2008–0738.

In the assessm nt, the A ency assum d that the residue level of the inert ingredient w uld be no higher than the highest tolerance for a given com dity. Im licit in this assum tion is that there w uld be sim lar rates of degradation (if any) betw en the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances w uld be no higher than the concentration of the active ingredient.

The A ency believes the assum tions used to estim te dietary exposures lead to an extrem ly conservative assessm nt of dietary risk due to a series of com ounded conservatism . First, assum ng that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient w ll overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50% of the product and often can be m ch higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a com ination of different inert ingredients used w ich additionally reduces the concentration of any single inert ingredient in the pesticide product in com arison w th the active ingredient. In the case of A SDs, EPA m de a specific adjustm nt to the dietary exposure assessm nt to account for the use lim tations of the am unt of A SDs that m y be in form lations (no m re than 30%) and assum d that the A SDs are at the m xim m lim tations rather than at equal quantities w th the active ingredient. This rem ins a very conservative assum tion because surfactants are generally used at levels far below these percentages. For exam le, EPA exam ned several of the pesticide products associated w th the tolerance/ com dity com ination w ich are the driver of the risk assessm nt and found that these products did not contain surfactants at levels greater than 2.25% and that none of the surfactants w re A SDs.

Second, the conservatism of this m thodology is com ounded by EPA s decision to assum that, for each com dity, the active ingredient w ich w ll serve as a guide to the potential level of inert ingredient residues is the active ingredient w th the highest tolerance level. This assum tion overstates residue values because it w uld be highly unlikely, given the high num er of inert ingredients, that a single inert ingredient or class of ingredients w uld be present at the level of the active ingredient in the highest tolerance for every com dity. Finally, a third com ounding conservatism is EPA s assum tion that all foods contain the inert ingredient at the highest tolerance level. In other w rds, EPA assum d 100% of all foods are treated w th the inert ingredient at the rate and m nner necessary to produce the highest residue legally possible for an active ingredient. In sum EPA chose a very conservative m thod for estim ting w at level of inert residue could be on food, and then used this m thodology to choose the highest possible residue that could be found on food and assum d that all food contained this residue. N consideration w s given to potential degradation betw en harvest and consum tion even though m nitoring data show that tolerance level residues are typically one to tw orders of m gnitude higher than actual residues in food w en distributed in com rce.

A cordingly, although sufficient inform tion to quantify actual residue levels in food is not available, the com ounding of these conservative assum tions w ll lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestim tes exposure in the absence of residue data.

ii. *Cancer.* The A ency used a qualitative SA database, DEREK11, to determ ne if there w re structural alerts for potential carcinogenicity of a

representative A SD. N structural alerts for carcinogenicity w re identified and the A SDs are not expected to be carcinogenic. Therefore a quantitative cancer exposure assessm nt is not necessary to assess cancer risk.

iii. *A ticipated residue and percent crop treated (PCT) inform tion.* EPA did not use anticipated residue or PCT inform tion in the dietary assessm nt for A SDs. Tolerance level residues or 100 PCT w re assum d for all food com dities.

2. *Dietary exposure from drinking w ter.* The A ency used screening level w ter exposure m dels in the dietary exposure analysis and risk assessm nt for A SDs in drinking w ter. These sim lation m dels take into account data on the physical, chem cal, and fate/transport characteristics of A SDs. Further inform tion regarding EPA drinking w ter m dels used in pesticide exposure assessm nt can be found at *http://w epa.gov/oppefed1/m dels/w ter/index.htm*

A screening level drinking w ter analysis, based on the Pesticide Root Zone M del/Exposure A alysis M deling System (PRZM EXA) w s perform d to calculate the estim ted drinking w ter concentrations (EDWCs) of A SDs. M deling runs on four surrogate inert ingredients using a range of physical chem cal properties that w uld bracket those of the A SDs w re conducted. M deled acute drinking w ter values ranged from 0.001 parts per billion (ppb) to 41 ppb. M deled chronic drinking w ter values ranged from 0.0002 ppb to 19 ppb. Further details of this drinking w ter analysis can be found at *http://w regulations.gov* in docum nt *A kyl A ne Polyalkoxylates (JITF CST 4 Inert Ingredients). H m n H alth Risk A sessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When Used as Inert Ingredients in Pesticide Form lations,* pages 18 and 70–72 in docket ID num er EPA H O P–2008–0738.

For the purpose of the screening level dietary risk assessm nt to support this request for an exem tion from the requirem nt of a tolerance for A SDs, a conservative drinking w ter concentration value of 100 ppb based on screening level m deling w s used to assess the contribution to drinking w ter for both the acute and chronic dietary risk assessm nts. These values w re directly entered into the dietary exposure m del.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this docum nt to refer to non-occupational, non-dietary exposure (e.g., for law and garden pest control, indoor pest control, term ticides, and flea and tick control on pets). A SDs are used as inert ingredients in pesticide products that are registered for specific uses that could result in indoor residential exposures and m y have uses as inert ingredients in pesticide products that m y result in outdoor residential exposures.

A screening level residential exposure and risk assessm nt w s com leted for products containing A SDs as inert ingredients. In this assessm nt, representative scenarios, based on end-use product application m thods and labeled application rates, w re selected. For each of the use scenarios, the A ency assessed residential handler (applicator) inhalation and derm l exposure for use scenarios w th high exposure potential (i.e., exposure scenarios w th high-end unit exposure values) to serve as a screening assessm nt for all potential residential pesticides containing A SDs. Sim larly, residential postapplication derm l and oral exposure assessm nts w re also perform d utilizing high-end exposure scenarios. Further details of this residential exposure and risk analysis can be found at *http://w regulations.gov* in docum nt *JITF Inert Ingredients. Residential and O cupational Exposure A sessm nt A gorithm and A sum tions A pendix for the H m n H alth Risk A sessm nts to Support Proposed Exem tion from the Requirem nt of a Tolerance When Used as Inert Ingredients in Pesticide Form lations* in docket ID num er EPA H O P–2008–0710.

4. *Cum lative effects from substances w th a com n m chanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, w en considering w ether to establish, m dify, or revoke a tolerance, the A ency consider ''available inform tion'' concerning the cum lative effects of a particular pesticide's residues and ''other substances that have a com n m chanism of toxicity.''

EPA has not found A SDs to share a com n m chanism of toxicity w th any other substances, and A SDs do not appear to produce a toxic m tabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assum d that A SDs do not have a com n m chanism of toxicity w th other substances. For inform tion regarding EPA s efforts to determ ne w ich chem cals have a com n m chanism of toxicity and to evaluate the cum lative effects of such chem cals, see EPA s w bsite at *http://w epa.gov/pesticides/cum lative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) m rgin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the com leteness of the database on toxicity and exposure unless EPA determ nes based on reliable data that a different m rgin of safety w ll be safe for infants and children. This additional m rgin of safety is com nly referred to as the FQ A SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF w en reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicity database consists of O PTS H rm nized Guideline 870.3650 (com ined repeated dose toxicity study w th the reproduction/developm ntal toxicity screening test) studies in rats conducted w th representative A Ds, as w ll as a 2–generation rat reproduction toxicity (O PTS H rm nized Guideline 870.3800) study and a rat developm ntal toxicity study conducted w th a representative A D.

In an O PTS H rm nized Guideline 870.3650 study conducted w th a representative A D, no increased susceptibility to the offspring of rats follow ng prenatal and postnatal exposure w s observed. In a second O PTS H rm nized Guideline 870.3650 study conducted w th another representative A D, there w s evidence of increased qualitative susceptibility as indicated by the increased num er of stillborn pups and pups dying w thin lactation day (LD) 4/5 and clinical observations (coldness to the touch, discolored heads, and a lack of nesting behavior) at 800 m /kg/day w ere lesions in the forestom ch and thym s atrophy w s observed in the parental anim ls. H w ver, this qualitative susceptibility seen in the O PTS H rm nized Guideline 870.3650 study does not indicate a heightened risk for infants and children because a clear N L (200 m /kg/day) w s established for developm ntal effects and an additional m rgin of safety is provided since the point of departure selected from the 2–generation rat reproduction study for chronic exposure is 87 m /kg/day.

In a rat developm ntal study w th A D, no m ternal or developm ntal toxicity w s observed at the lim t dose. In the 2–generation reproduction study w th A D, the only significant effects observed w re liver effects

characterized by dose-related decrease in absolute and relative liver w ight and an increased incidence in the num er of anim ls w th "m nim l" hepatocyte necrosis in m les. N treatm nt-related effects w re observed on reproduction or in the offspring.

There are no residual uncertainties identified in the exposure databases. The food exposure assessm nts are considered to be conservative. The food and drinking w ter assessm nt is not likely to underestim te exposure to any subpopulation, including those com rised of infants and children.

3. *Conclusion.* EPA has determ ned that reliable data show the safety of infants and children w uld be adequately protected if the FQ A SF w re reduced to 1X. That decision is based on the follow ng findings:

i. The toxicity database for A SDs is considered adequate for assessing the risks to infants and children (the available studies are described in U it IV.D.2.).

ii. N susceptibility w s dem nstrated in the offspring in the reproductive/ developm ntal screening test portion of an O PTS H rm nized Guideline 870.3650 study w th one A D follow ng prenatal and postnatal exposure at 800 m /kg/day.

iii. A though increased qualitative susceptibility w s dem nstrated in the offspring in a reproductive/ developm ntal screening test portion of an O PTS H rm nized Guideline 870.3650 study w th another A D, the A ency did not identify any residual uncertainties after establishing toxicity endpoints and traditional U s to be used in the risk assessm nt of the A SDs.

iv. There is no indication that A SDs are neurotoxic chem cals and thus there is no need for a developm ntal neurotoxicity study or additional U s to account for neurotoxicity.

v. There are no residual uncertainties identified in the exposure databases. The food and drinking w ter assessm nt is not likely to underestim te exposure to any subpopulation, including those com rised of infants and children. The food exposure assessm nts are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100 PCT is assum d for all crops. EPA also m de conservative (protective) assum tions in the ground and surface w ter m deling used to assess exposure to A SDs in drinking w ter. EPA used sim larly conservative assum tions to assess postapplication exposure of children as w ll as incidental oral exposure of toddlers. These assessm nts w ll not underestim te the exposure and risks posed by A SDs.

E. A gregate Risks and Determ nation of Safety

EPA determ nes w ether acute and chronic pesticide exposures are safe by com aring aggregate exposure estim tes to the aPA and cPA . The aPA and cPA represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPA and cPA by dividing the PO by all applicable U s. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estim ted aggregate exposure. Short-, interm diate-, and chronic-term risks are evaluated by com aring the estim ted aggregate food, w ter, and residential exposure to the PO to ensure that the M called for by the product of all applicable U s is not exceeded.

In conducting this aggregate risk assessm nt, the A ency has incorporated the petitioner's requested use lim tations of A SDs as inert ingredients in pesticide product form lations into its exposure assessm nt. Specifically the petition includes a use lim tation of A SDs at not m re than 30% by w ight in pesticide form lations.

1. *A ute risk.* A acute aggregate risk assessm nt takes into account exposure estim tes from acute dietary consum tion of food and drinking w ter. N adverse effects attributable to a single exposure to the A SDs w re seen in the toxicity databases, therefore, A SDs are not expected to pose an acute risk.

2. *Chronic risk.* A chronic aggregate risk assessm nt takes into account exposure estim tes from chronic dietary consum tion of food and drinking w ter. U ing the exposure assum tions discussed in this unit for chronic exposure, and the use lim tations of not m re than 30% by w ight in pesticide form lations, the chronic dietary exposure from food and w ter to A SDs is 13% of the cPA for the U S. population and 43% of the cPA for children 1–2 yrs old, the m st highly exposed population subgroup.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and w ter (considered to be a background exposure level).

A SDs are used as inert ingredients in pesticide products that are currently registered for uses that could result in short-term residential exposure and the A ency has determ ned that it is appropriate to aggregate chronic exposure through food and w ter w th short-term residential exposures to A SDs.

U ing the exposure assum tions described in this unit for short-term exposures, EPA has concluded the com ined short-term food, w ter, and residential exposures aggregated result in aggregate M s of 130 and 140, for adult m les and fem les respectively, for a com ined high-end derm l and inhalation handler exposure w th a high-end postapplication derm l exposure and an aggregate M of 110 for children for a com ined turf derm l exposure w th hand-to-m uth exposure.

4. *Interm diate-term risk.* Interm diate-term aggregate exposure takes into account interm diate-term residential exposure plus chronic exposure to food and w ter (considered to be a background exposure level).

A SDs are used as inert ingredients in pesticide products that are currently registered for uses that could result in interm diate-term residential exposure and the A ency has determ ned that it is appropriate to aggregate chronic exposure through food and w ter w th interm diate-term residential exposures to A SDs.

U ing the exposure assum tions described in this unit for interm diate-term exposures, EPA has concluded the com ined interm diate-term food, w ter, and residential exposures aggregated result in aggregate M s of 270 and 280, for adult m les and fem les respectively, for a com ined high-end derm l and inhalation handler exposure w th a high-end postapplication derm l exposure and an M of 110 for children for a com ined high-end derm l exposure w th hand-to-m uth exposure.

5. *A gregate cancer risk for U.S. population.* Based on the lack of structural alerts for carcinogenicity, A SDs are not expected to pose a cancer risk to hum ns.

6. *Determ nation of safety.* Based on these risk assessm nts, EPA concludes that there is a reasonable certainty that no harm w ll result to the general population or to infants and children from aggregate exposure to residues of A SDs.

V. Other Considerations

A A alytical Enforcem nt M thodology

A analytical m thod is not required for enforcem nt purposes since the A ency is establishing an exem tion from the requirem nt of a tolerance w thout any num rical lim tation.

B. International Residue Lim ts

The A ency is not aw re of any country requiring a tolerance for A SDs nor have any CO EX M xim m Residue Levels been established for any food crops at this tim .

VI. Conclusion

Therefore, exem tions from the requirem nt of a tolerance are established for residues of A Ds w en used as inert ingredients in pesticide form lations applied to grow ng crops only under 40 CFR 180.920 and residues of A Ds w en used as inert ingredients in raw agricultural com dities, grow ng crops, and anim ls under 40 CFR 180.910, 40 CFR 180.920, and 40 CFR 180.930.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition subm tted to the A ency. The O fice of M nagem nt and Budget (O) has exem ted these types of actions from review under Executive O der 12866, entitled *Regulatory Planning and Review* (58 FR 51735, O tober 4, 1993). Because this final rule has been exem ted from review under Executive O der 12866, this final rule is not subject to Executive O der 13211, entitled *A tions Concerning Regulations That Significantly A fect Energy Supply, Distribution, or Use* (66 FR 28355, M y 22, 2001) or Executive O der 13045, entitled *Protection of Children from Environm ntal H alth Risks and Safety Risks* (62 FR 19885, A ril 23, 1997). This final rule does not contain any inform tion collections subject to O approval under the Paperw rk Reduction A t (PRA , 44 U S.C. 3501 *et seq.*, nor does it require any special considerations under Executive O der 12898, entitled *Federal A tions to A dress Environm ntal Justice in M nority Populations and Low-Incom Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exem tions 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 requirem nts of the Regulatory Flexibility A t (RFA (5 U S.C. 601 *et seq.*) do not apply.

This final rule directly regulates grow rs, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of pow r and responsibilities established by Congress in the preem tion provisions of section 408(n)(4) of FFDCA A such, the A ency has determ ned that this action w ll not have a substantial direct effect on States or tribal governm nts, on the relationship betw en the national governm nt and the States or tribal governm nts, or on the distribution of pow r and responsibilities am ng the various levels of governm nt or betw en the Federal Governm nt and Indian tribes. Thus, the A ency has determ ned that Executive O der 13132, entitled *Federalism* (64 FR 43255, A gust 10, 1999) and Executive O der 13175, entitled *Consultation and Coordination w th Indian Tribal Governm nts* (65 FR 67249, N vem er 9, 2000) do not apply to this final rule. In addition, this final rule does not im ose any enforceable duty or contain any unfunded m ndate as described under Title II of the U funded M ndates Reform A t of 1995 (U A (Public Law 104–4).

This action does not involve any technical standards that w uld require A ency consideration of voluntary consensus standards pursuant to section 12(d) of the N tional Technology Transfer and A vancem nt A t of 1995 (N TA , Public Law 104–113, section 12(d) (15 U S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review A t, 5 U S.C. 801 *et seq.*, generally provides that before a rule m y take effect, the agency prom lgating the rule m st subm t a rule report to each H use of the Congress and to the Com troller General of the U ited States. EPA w ll subm t a report containing this rule and other required inform tion to the U S. Senate, the U S. H use of Representatives, and the Com troller General of the U ited States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''m jor rule'' as defined by 5 U S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environm ntal protection, A m nistrative practice and procedure, A ricultural com dities, Pesticides and pests, Reporting and recordkeeping requirem nts.

Dated: July 20, 2009.

G Jeffrey Herndon,

A ting Director, Registration Division, O fice of Pesticide Program .

■ Therefore, 40 CFR chapter I is am nded as follow :

PART 180—[AM NDED]

■ 1. The authority citation for part 180 continues to read as follow :

Authority: 21 U S.C. 321(q), 346a and 371.

■ 2. In § 180.910, the table is am nded by adding alphabetically the follow ng inert ingredients to read as follow :

§ 180.910 nert ingredients used pre- and post-harvest; exem tions from the requirem nt of a tolerance.

* * * * *

Inert ingredients	im ts	ses
*		
α-Alkyl(C_6–C_{15})-ω-hydroxypoly(oxyethylene)sulfate, and its am nium calcium m gnesium potassium sodium and zinc salts, poly(oxyethylene) content averages 2–4 m les (CAS Reg. Nos. 3088–31–1, 9004–82–4, 9004–84–6, 13150–00–0, 25446–78–0, 26183–44–8, 32612–48–9, 50602–06–7, 62755–21–9, 68424–50–0, 68511–39–7, 68585–34–2, 68611–55–2, 68891–38–3, 73665–22–2).	Not to exceed 30% of pesticide form lation.	Surfactants, related adjuvants of surfactants
*		

■ 3. In § 180.920, the table is am nded by adding alphabetically the follow ng inert ingredients to read as follow :

§ 180.920 nert ingredients used pre-harvest; exem tions from the requirem nt of a tolerance.

* * * * *

Inert ingredients	im ts	ses
*		
α-Alkyl (m nim m $_6$ linear, ranched, aturated nd/or nsaturated)-ω-hydroxypolyoxyethylene polym r with or without polyoxypropylene, m xture of di- and m nohydrogen phosphate esters and the corresponding am nium calcium m gnesium m noethanolam ne, potassium sodium and zinc salts of the phosphate esters; m nim m oxyethylene content is 2 m les; m nim m oxypropylene content is 0 m les (CAS Reg. Nos. 9046–01–9, 37280–82–3, 39464–66–9, 42612–52–2, 50643–20–4, 52019–36–0, 58318–92–6, 60267–55–2, 61837–79–4, 67711–84–6, 68070–99–5, 68071–35–2, 68071–17–0, 68130–47–2, 68186–37–8, 68186–36–7, 68311–02–4, 68425–73–0, 68458–48–0, 68511–37–5, 68610–65–1, 68585–36–4, 68649–29–6, 68815–11–2, 68908–64–5, 68891–13–4, 73038–25–2, 78330–24–2, 108818–88–8, 154518–39–5, 317833–96–8, 873662–29–4, 936100–29–7, 936100–30–0).	Not to exceed 30% of pesticide form lation.	Surfactants, related adjuvants of surfactants
*		

■ 4. In § 180.930, the table is am nded by adding alphabetically the follow ng inert ingredients to read as follow :

§ 180.930 nert ingredients applied to anim ls; exem tions from the requirem nt of a tolerance.

* * * * *

Inert ingredients	im ts	ses
*		
α-Alkyl(C_6-C_{15})-ω-hydroxypoly(oxyethylene)sulfate, and its am nium calcium m gnesium potassium sodium and zinc salts, poly(oxyethylene) content averages 2–4 m les (CAS Reg. Nos. 3088–31–1, 9004–82–4, 9004–84–6, 13150–00–0, 25446–78–0, 26183–44–8, 32612–48–9, 50602–06–7, 62755–21–9, 68424–50–0, 68511–39–7, 68585–34–2, 68611–55–2, 68891–38–3, 73665–22–2).	Not to exceed 30% of pesticide form lation.	Surfactants, related adjuvants of surfactants
*		

[FR Doc. E9–18033 Filed 7–28–09; 8:45 am
BILLING CO E 6560–50–S

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 180

[EPA–HQ O P–2009–0046; FRL–8428–9]

N-alkyl (C_8-C_{18}) Prim ry Am nes and Acetate Salts; Exem tion from the Requirem nt of a Tolerance

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Final rule.

SUM RY: This regulation establishes an exem tion from the requirem nt of a tolerance for residues of N alkyl (C_8-C_{18}) prim ry am nes and acetate salts w ere the alkyl group is linear and m y be saturated and/or unsaturated, herein referred to in this docum nt as N A , w en used as inert ingredients for pre-harvest uses under 40 CFR 180.920 at a m xim m concentration in form lated end-use products of 10% by w ight in herbicide products, 4% by w ight in insecticide products, and 4% by w ight in fungicide products. The Joint Inerts Task Force (JITF), Cluster Support Team N m er 25 (CST 25), subm tted a petition to EPA under the Federal Food, Drug, and Cosm tic A t (FFDCA , requesting an exem tion from the requirem nt of a tolerance. This regulation elim nates the need to establish a m xim m perm ssible level for residues of N A .

DATES: This regulation is effective July 29, 2009. O jections and requests for hearings m st be received on or before Septem er 28, 2009, and m st be filed in accordance w th the instructions provided in 40 CFR part 178 (see also U it I.C. of the **SUPPLEM NTARY INFO M TIO **).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) num er EPA H O P–2009–0046. A l docum nts in the docket are listed in the docket index available at *http://w regulations.gov*. A though listed in the index, som inform tion is not publicly available, e.g., Confidential Business Inform tion (CBI) or other inform tion w ose disclosure is restricted by statute. Certain other m terial, such as copyrighted m terial, is not placed on the Internet and w ll be publicly available only in hard copy form Publicly available docket m terials are available in the electronic docket at *http://w regulations.gov*, or, if only available in hard copy, at the O P Regulatory Public Docket in Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA The Docket Facility is open from 8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays. The Docket Facility telephone num er is (703) 305–5805.

FO URTHER NFO M TIO O TACT: Kerry Leifer, Registration Division (7505P), O fice of Pesticide Program , Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001; telephone num er: (703) 308–8811; e-m il address: *leifer.kerry@epa.gov*.

SUPPLEM NTARY NFO M TIO : I

I. G neral Inform tion

A Does this A tion A ply to M ?

You m y be potentially affected by this action if you are an agricultural producer, food m nufacturer, or pesticide m nufacturer. Potentially affected entities m y include, but are not lim ted to those engaged in the follow ng activities:

- rop production (N CS code 111).
- im l production (N CS code A 112).
- ood m nufacturing (N CS codeF 311).
- esticide m nufacturing (N CS P code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. O her types of entities not listed in this unit could also be affected. The N rth A rican Industrial Classification System

Exhibit 29

[FR Doc. E9–18725 Filed 8–4–09; 8:45 am
BILLING CO E 6560–50–S

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 180

[EPA–HQ O P–2009–0042; FRL–8424–4]

M thyl Poly(O yethylene)C_8–C_{18} Alkylam nium Chlorides; Exem tion from the Requirem nt of a Tolerance

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Final rule.

SUM RY: This regulation establishes an exem tion from the requirem nt of a tolerance for residues of m thyl poly(oxyethylene)C_8–C_{18} alkylam nium chlorides w ere the poly(oxyethylene) content is n=2–15 and w ere C_8–C_{18} alkyl is linear and m y be saturated or unsaturated, herein referred to in this docum nt as m thyl poly(oxyethylene)C_8–C_{18} alkylam nium chlorides (M O s), w en used as an inert ingredient in pesticide form lations for pre-harvest uses under 40 CFR 180.920 at a m xim m of 10% by w ight in herbicide form lations and 5% by w ight in all other form lations. The Joint Inerts Task Force (JITF), Cluster Support Team (CST N . 7), subm tted a petition to EPA under the Federal Food, Drug, and Cosm tic A t (FFDCA , requesting an exem tion from the requirem nt of a tolerance. This regulation elim nates the need to establish a m xim m perm ssible level for residues of M O s.

DATES: This regulation is effective A gust 5, 2009. O jections and requests for hearings m st be received on or before O tober 5, 2009, and m st be filed in accordance w th the instructions provided in 40 CFR part 178 (see also U it I.C. of the **SUPPLEM NTARY INFO M TIO **).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) num er EPA H O P–2009–0042. A l docum nts in the docket are listed in the docket index available at *http://w regulations.gov*. A though listed in the index, som inform tion is not publicly available, e.g., Confidential Business Inform tion (CBI) or other inform tion w ose disclosure is restricted by statute. Certain other m terial, such as copyrighted m terial, is not placed on the Internet and w ll be publicly available only in hard copy form Publicly available docket m terials are available in the electronic docket at *http://w regulations.gov*, or, if only available in hard copy, at the O P Regulatory Public Docket in Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA The Docket Facility is open from 8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays. The Docket Facility telephone num er is (703) 305–5805.

FO URTHER NFO M TIO O TACT: Kerry Leifer, Registration Division (7505P), O fice of Pesticide Program , Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001; telephone num er: (703) 308–8811; e-m il address: *leifer.kerry@epa.gov*.

SUPPLEM NTARY NFO M TIO : I

I. G neral Inform tion

A Does this A tion A ply to M ?

You m y be potentially affected by this action if you are an agricultural producer, food m nufacturer, or pesticide m nufacturer. Potentially affected entities m y include, but are not lim ted to those engaged in the follow ng activities:

- Crop production (N CS code 111).
- A im l production (N CS code 112).
- Food m nufacturing (N CS code 311).
- Pesticide m nufacturing (N CS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. O her types of entities not listed in this unit could also be affected. The N rth A rican Industrial Classification System (N CS) codes have been provided to assist you and others in determ ning w ether this action m ght apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FO URTHER INFO M TIO O TACT**.

B. H w Can I A cess Electronic Copies of this Docum nt?

In addition to accessing electronically available docum nts at *http://w regulations.gov*, you m y access this **Federal Register** docum nt electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://w epa.gov/fedrgstr*. You m y also access a frequently updated electronic version of EPA s tolerance regulations at 40 CFR part 180 through the Governm nt Printing O fice's e-CFR cite at *http://w gpoaccess.gov/ecfr*. To access the O PTS H m nized Guidlines referenced in this docum nt, go directly to the guidelines at *http://w epa.gpo/opptsfrs/hom / suidelin.htm*

C. Can I File an O jection or H aring Request?

U der section 408(g) of FFDCA 21 U S.C. 346a, any person m y file an objection to any aspect of this regulation and m y also request a hearing on those objections. You m st file your objection or request a hearing on this regulation in accordance w th the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA you m st identify docket ID num er EPA H O P–2009–0042 in the subject line on the first page of your subm ssion. A l requests m st be in w iting, and m st be m iled or delivered to the H aring Clerk as required by 40 CFR part 178 on or before O tober 5, 2009.

In addition to filing an objection or hearing request w th the H aring Clerk as described in 40 CFR part 178, please subm t a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES.** Inform tion not m rked confidential pursuant to 40 CFR part 2 m y be disclosed publicly by EPA w thout prior notice. Subm t this copy, identified by docket ID num er EPA H O P–2009–0042, by one of the follow ng m thods:

- *Federal eRulem king Portal*: *http://w regulations.gov*. Follow the on-line instructions for subm tting com nts.
- *M il*: O fice of Pesticide Program (O P) Regulatory Public Docket (7502P), Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001.
- *Delivery*: O P Regulatory Public Docket (7502P), Environm ntal Protection A ency, Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA Deliveries are only accepted during the Docket Facility's norm l hours of operation (8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays). Special arrangem nts should be m de for deliveries of boxed inform tion. The Docket Facility telephone num er is (703) 305–5805.

II. Background

In the **Federal Register** of M rch 4, 2009 (74 FR 9397) (FRL–8401–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA 21 U S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7518) by The JITF, CST N . 7, c/o CropLife A rica, 1156 15th St., N , Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.920 be

am nded by establishing exem tions from the requirem nt of a tolerance for residues of the inert ingredient m thyl poly(oxyethylene)C_8–C_{18} alkylam nium chlorides w ere the poly(oxyethylene) content is n=2–15 and w ere C_8–C_{18} alkyl is linear and m y be saturated or unsaturated (M O s) for pre-harvest uses at a m xim m of 10% by w ight in herbicide form lations and 5% by w ight in all other form lations. That notice referenced a sum ry of the petition prepared by The JITF, CST N . 7, the petitioner, w ich is available to the public in the docket, *http:// w regulations.gov*.

The A ency received tw com nts in response to the notice of filing. Both com nts w s received from private citizens w o opposed the authorization to sell any pesticide that leaves a residue on food. The A ency understands the com nters' concerns and recognizes that som individuals believe that no residue of pesticides should be allow d. H w ver, under the existing legal fram w rk provided by section 408 of FFDCA EPA is authorized to establish pesticide tolerances or exem tions w ere persons seeking such tolerances or exem tions have dem nstrated that the pesticide m ets the safety standard im osed by that statute.

This petition w s subm tted in response to a final rule of A gust 9, 2006, (71 FR 45415) (FRL–8084–1) in w ich the A ency revoked, under section 408(e)(1) of the FFDCA the existing exem tions from the requirem nt of a tolerance for residues of certain inert ingredients because of insufficient data to m ke the determ nation of safety required by section 408(b)(2) of FFDCA The expiration date for the tolerance exem tions subject to revocation w s A gust 9, 2008, w ich w s later extended A gust 9, 2009 by a final rule published in the **Federal Register** of A gust 4, 2008. (73 FR 45312) (FRL–8372–7) to allow for data to be subm tted to support the establishm nt of tolerance exem tions for these inert ingredients prior to the effective date of the tolerance exem tion revocation.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not lim ted to, the follow ng types of ingredients (except w en they have a pesticidal efficacy of their ow): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polym rs and fatty acids; carriers such as clay and diatom ceous earth; thickeners such as carrageenan and m dified cellulose; w tting, spreading, and dispersing agents; propellants in aerosol dispensers; m croencapsulating agents; and em lsifiers. The term ''inert'' is not intended to im ly nontoxicity; the ingredient m y or m y not be chem cally active. Generally, EPA has exem ted inert ingredients from the requirem nt of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessm nt and Determ nation of Safety

Section 408(b)(2)(A (i) of FFDCA allow EPA to establish an exem tion from the requirem nt of a tolerance (the legal lim t for a pesticide chem cal residue in or on a food) only if EPA determ nes that the tolerance is ''safe.'' Section 408(b)(2)(A (ii) of FFDCA defines ''safe'' to m an that ''there is a reasonable certainty that no harm w ll result from aggregate exposure to the pesticide chem cal residue, including all anticipated dietary exposures and all other exposures for w ich there is reliable inform tion.'' This includes exposure through drinking w ter and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chem cal residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm w ll result to infants and children from aggregate exposure to the pesticide chem cal residue. . . .

EPA perform a num er of analyses to determ ne the risks from aggregate exposure to pesticide residues. First, EPA determ nes the toxicity of pesticides. Second, EPA exam nes exposure to the pesticide through food, drinking w ter, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent w th section 408(b)(2)(D) of FFDCA and the factors specified in section 408(b)(2)(D) of FFDCA EPA has review d the available scientific data and other relevant inform tion in support of this action. EPA has sufficient data to assess the hazards of and to m ke a determ nation on aggregate exposure for the petitioned-for exem tion from the requirem nt of a tolerance for residues of M O s w en used as inert ingredients in pesticide form lations for pre-harvest uses at a m xim m of 10% by w ight in herbicide form lations and 5% by w ight in all other form lations. EPA s assessm nt of exposures and risks associated w th establishing tolerances follow .

A Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, com leteness, and reliability as w ll as the relationship of the results of the studies to hum n risk. EPA has also considered available inform tion concerning the variability of the sensitivities of m jor identifiable subgroups of consum rs, including infants and children.

The toxicity data available on the M O s consists of acute toxicity studies, m tagenicity studies, and an O PTS H rm nized Guideline 870.3650 com ined repeated dose toxicity study w th the reproduction/developm ntal toxicity screening test. The m jority of the M O com ounds are reported as ''not acutely toxic'' for lethality by the oral and derm l routes of exposure (Toxicity Category III). H w ver, CA Reg. N . 70750–47–9, the representative test com ound, is m re toxic by the oral and derm l routes (Toxicity Category II). A l M O s are severely irritating to the eye (Toxicity Category I), and the M O identified by CA Reg. N .70750–47–9 (quatenary am nium com ounds, coco alkylbis(hydroxyethyl)m thy1, chlorides) is severely irritating to the skin. Inhalation data on tw of the M O s indicate irritation at high doses.

The O PTS H rm nized Guideline 870.3650 study on the representative surfactant, (CA Reg. N . 70750–47–9) dem nstrated severe toxicity in rats, as evidenced by deaths of all test subjects at 100 m lligram /kilogram day (m /kg/day) after 5 days, and deaths of 5 out of 10 fem les at 50 m /kg/day after 6–8 days of exposure. Given the extrem ly corrosive nature of the test m terial, the A ency believes that the high m rtality rate is secondary to the forestom ch lesions seen in the rats. Further, the A ency notes that the severity of the effects m y be related to the unique anatom of the rats. H m ns do not have a forestom ch w ich serves as a storage reservoir in rodents; therefore, effects seen in the rat forestom ch are likely to be significantly m re severe than w at w uld be expected from the com ound in the glandular stom chs in hum ns and therefore, have less relevance to hum ns.

The no observed adverse effect level (N L) for developm ntal and reproductive toxicity is 25 m /kg/day, the low st dose tested (LDT). A though no reproductive or developm ntal effects w re observed at the next higher dose of 50 m /kg/day, the evaluation at

this dose level included only 5 surviving fem le anim ls. While the actual low st observed adverse effect level (LO L) for reproductive developm ntal effects m y be higher, or reproductive developm ntal effects m y not occur at all as a result of exposure to this chem cal, in the absence of a sufficient num er of anim ls to assess, the A ency has conservatively assum d that if m re anim ls had been available at the m d-dose, developm ntal or reproductive toxicity m ght have been observed. There are no concerns for sensitivity of offspring.

There w s no evidence of neurotoxicity in this study; functional-observational battery and m tor-activity data w re sim lar in all the treatm nt groups. Liver enzym s w re elevated but w re not accom anied by m croscopic lesions or increased organ w ight and w re not considered adverse. N carcinogenicity studies are available for the M O s. A qualitative structure activity relationship database, DEREK Version 11, identified no structural alerts suggestive of carcinogenicity.

Specific inform tion on the studies received and the nature of the adverse effects caused by M O s as w ll as the N L and the LO L from the toxicity studies can be found at *http://w regulations.gov* in docum nt M O s–JITF CST N . 7 Inert Ingredients). *H m n H alth Risk A sessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When Used as Inert Ingredients in Pesticide Form lations* pages 9–13 and pages 25–26 in docket ID num er EPA H O P–2009–0042.

B. Toxicological Endpoints

For hazards that have a threshold below w ich there is no appreciable risk, a toxicological point of departure (PO) is identified as the basis for derivation of reference values for risk assessm nt. The PO m y be defined as the highest dose tested (H T) at w ich the N L in the toxicology study identified as appropriate for use in risk assessm nt. H w ver, if a N L cannot be determ ned, the low st dose at w ich adverse effects of concern are identified (the LO L) or a benchm rk dose (BM) approach is som tim s used for risk assessm nt. U certainty/safety factors (U s) are used in conjunction w th the PO to take into account uncertainties inherent in the extrapolation from laboratory anim l data to hum ns and in the variations in sensitivity am ng m m ers of the hum n population as w ll as other unknow s. Safety is assessed for acute and chronic dietary risks by com aring aggregate food and w ter exposure to the pesticide to the acute population adjusted dose (aPA) and chronic population adjusted dose (cPA). The aPA and cPA are calculated by dividing the PO by all applicable U s. A gregate short-term interm diate-term and chronic-term risks are evaluated by com aring food, w ter, and residential exposure to the PO to ensure that the m rgin of exposure (M) called for by the product of all applicable U s is not exceeded. This latter value is referred to as the level of concern (LO).

For non-threshold risks, the A ency assum s that any am unt of exposure w ll lead to som degree of risk. Thus, the A ency estim tes risk in term of the probability of an occurrence of the adverse effect greater than that expected in a lifetim . For m re inform tion on the general principles EPA uses in risk characterization and a com lete description of the risk assessm nt process, see *http://w epa.gov/pesticides/factsheets/riskassess.htm*

A sum ry of the toxicological endpoints for M O s used for hum n health risk assessm nt is show in Table 1 of this unit.

TABLE 1.—SUM RY O TOXICOLO ICAL DO ES ND ENDPOINTS O M O CS O USE IN HUM N HEALTH RISK ASSESSM NT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessm nt	Study and Toxicological Effects
Acute dietary (all populations)	Acute toxicity was not identified.		
Chronic dietary (all populations)	NO EL = 25 m /kg/day UF_A = 10x UF_H = 10x Food quality protection act (FQPA) SF = 1x	Chronic RfD = 0.25 m /kg/day cPAD = 0.25 m /kg/day	LO EL = 50 m /kg/day based on stom ch inflam tion and m rtality associated with the forestom ch inflam tion
Incidental oral (short-term and interm diate-term)	NO EL= 25 m /kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for M = 100	LO EL = 50 m /kg/day based on stom ch inflam tion and m rtality associated with the forestom ch inflam tion.
Derm l and inhalation (all durations)	Quantitative assessm nt not required: Cluster is corrosive irritating and exposure will be self limiting; expected low-derm l and inhalation absorptions; product is used in low percentages in household products (i.e., low exposure).		
Cancer (oral, derm l, inhalation)	Classification: No anim l toxicity data available for an assessm nt. Based on SAR analysis, M O Cs is not expected to be carcinogenic.		

PO = A data point or an estim ted point that is derived from observed dose-response data and used to m rk the beginning of extrapolation to determine risk associated with lower environm ntally relevant hum n exposures. NO EL = no observed adverse effect level. LO EL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from anim l to hum n (interspecies). UF_H = potential variation in sensitivity am ng m m ers of the hum n population (intraspecies). PAD = population adjusted dose (a=acute, c=chronic). FQPA SF = FQPA Safety Factor. RfD = reference dose. M = m rgin of exposure. LOC = level of concern. N/A = not applicable.

C. Exposure A sessm nt

Sufficient data w re provided on the chem cal identity of the M O s; how ver, lim ted data are available on the m tabolism and environm ntal degradation of these com ounds. The A ency relied collectively on inform tion provided on the representative chem cal structures, the generic cluster structures, the subm tted physicochem cal data, structure-activity relationship inform tion, as w ll as

inform tion on other surfactants and chem cals of sim lar size and functionality to determ ne the residues of concern for these inert ingredients. The residues of concern for risk assessm nt purposes are the parent com ounds only.

The registrant selected CA Reg. N . 70750–47–9, as the test com ound because the coco alkyl encom asses the broad range of C_8–C_{18} alkyl chain included in the descriptor. The A ency concluded that the cluster grouping w s appropriate. Further, the A ency also concluded that it is unlikely that any potential environm ntal degradates that w uld be found in food and w ter w ll be m re toxic than the parent com ound. Residue estim tes used in the dietary risk assessm nt w re chosen to represent an upper bound on the com ined residues of parent and any potential m tabolite or degradate of concern.

Q antitative derm l or inhalation risk assessm nts w re not be perform d for residential exposures because the M O s are highly corrosive irritating, and therefore, exposure w ll be self-lim ting and w ll be regulated based on labeling of the form lations. There is not a significant concern for derm l or inhalation exposures due to expected low derm l and inhalation absorptions and the fact that the product is used in low percentages in household products (i.e., low exposure). A aggregate assessm nt need only be conducted for food, w ter, and incidental oral exposures.

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to M O s, EPA considered exposure under the petitioned-for exem tions from the requirem nt of a tolerance. EPA assessed dietary exposures from M O s in food as follow :

i. *A ute exposure.* N adverse effects attributable to a single exposure of M O s w s seen in the toxicity databases. Therefore, acute dietary risk assessm nts for M O s is not necessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessm nt, EPA used food consum tion inform tion from the U ited States Departm nt of A riculture (U DA 1994–1996 and 1998 N tionw de Continuing Surveys of Food Intake by Individuals (CSFII). A to residue levels in food, no residue data w re subm tted for M O s. In the absence of specific residue data, EPA has developed an approach w ich uses surrogate inform tion to derive upper bound exposure estim tes for the subject inert ingredient. U per bound exposure estim tes are based on the highest tolerance for a given com dity from a list of high-use insecticides, herbicides, and fungicides. A com lete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the m m randum entitled *A kyl A nes Polyalkoxylates (Cluster 4): A ute and Chronic A gregate (Food and Drinking Water) Dietary Exposure and Risk A sessm nts for the Inerts.* (D361707, S. Piper, 2/25/09) and can be found at *http://w regulations.gov* in docket ID num er EPA H O P–2008–0738.

In the dietary exposure assessm nt, the A ency assum d that the residue level of the inert ingredient w uld be no higher than the highest tolerance for a given com dity. Im licit in this assum tion is that there w uld be sim lar rates of degradation (if any) betw en the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances w uld be no higher than the concentration of the active ingredient.

The A ency believes the assum tions used to estim te dietary exposures lead to an extrem ly conservative assessm nt of dietary risk due to a series of com ounded conservatism . First, assum ng that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient w ll overstate exposure. The concentrations of active ingredient in agricultural products is generally at least 50% of the product and often can be m ch higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a com ination of different inert ingredients used w ich additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient. In the case of M O s, EPA m de a specific adjustm nt to the dietary exposure assessm nt to account for the use lim tations of the am unt of M O s that m y be in form lations (no m re than 10% by w ight in herbicide form lations) and assum d that the M O s are present at the m xim m lim tations rather than at equal quantities w th the active ingredient. This rem ins a very conservative assum tion because surfactants are generally used at levels far below this percentage.

Second, the conservatism of this m thodology is com ounded by EPA s decision to assum that, for each com dity, the active ingredient w ich w ll serve as a guide to the potential level of inert ingredient residues is the active ingredient w th the highest tolerance level. This assum tion overstates residue values because it w uld be highly unlikely, given the high num er of inert ingredients, that a single inert ingredient or class of ingredients w uld be present at the level of the active ingredient in the highest tolerance for every com dity. Finally, a third com ounding conservatism is EPA s assum tion that all foods contain the inert ingredient at the highest tolerance level. In other w rds, EPA assum d 100% of all foods are treated w th the inert ingredient at the rate and m nner necessary to produce the highest residue legally possible for an active ingredient. In sum ry, EPA chose a very conservative m thod for estim ting w at level of inert residue could be on food, then used this m thodology to choose the highest possible residue that could be found on food and assum d that all food contained this residue. N consideration w s given to potential degradation betw en harvest and consum tion even though m nitoring data show that tolerance level residues are typically one to tw orders of m gnitude higher than actual residues in food w en distributed in com rce.

A cordingly, although sufficient inform tion to quantify actual residue levels in food is not available, the com ounding of these conservative assum tions w ll lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestim tes exposure in the absence of residue data.

iii. *Cancer.* The A ency used a qualitative SA database, DEREK11, to determ ne if there w re structural alerts suggestive of carcinogenicity. N structural alerts for carcinogenicity w re identified. M O s are not expected to be carcinogenic. Therefore, a cancer dietary exposure assessm nt is not necessary to assess cancer risk.

iv. *A ticipated residue and percent crop treated (PCT) inform tion.* EPA did not use anticipated residue and PCT inform tion in the dietary assessm nt for M O s. Tolerance level residues and 100 PCT w re assum d for all food com dities.

2. *Dietary exposure from drinking w ter.* The A ency used screening level w ter exposure m dels in the dietary exposure analysis and risk assessm nt for M O s in drinking w ter. These sim lation m dels take into account data on the physical, chem cal, and fate transport characteristics of M O s. Further inform tion regarding EPA drinking w ter m dels used in the pesticide exposure assessm nt can be

found at *http://w epa.gov/oppefed1/m dels/w ter/index.htm*

A screening level drinking w ter analysis, based on the Pesticide Root Zone M del /Exposure A alysis M deling System (PRZM EXA) w s perform d to calculate the estim ted drinking w ter concentrations (EDWCs) of M O s. M deling runs on four surrogate inert ingredients using a range of physical chem cal properties that w uld bracket those of M O s w re conducted. M deled acute drinking w ter values ranged from 0.001 parts per billion (ppb) to 41 ppb. M deled chronic drinking w ter values ranged from 0.0002 ppb to 19 ppb. Further details of this drinking w ter analysis can be found at *http://w regulations.gov* in the docum nt M O s– JITF, (CST N . 7 Inert Ingredients). *H m n H alth Risk A sessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When Used as Inert Ingredients in Pesticide Form lations,* pages 13–14 and 28–46 in docket ID num er EPA H O P–2009–0042.

For the purpose of the screening level dietary risk assessm nt to support this request for an exem tion from the requirem nt of a tolerance for M O s, a conservative drinking w ter concentration value of 100 ppb based on screening level m deling w s used to assess the contribution to drinking w ter for chronic dietary risk assessm nts for the parent com ounds and for the m tabolites of concern. These values w re directly entered into the dietary exposure m del.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this docum nt to refer to non-occupational, non-dietary exposure (e.g., for law and garden pest control, indoor pest control, term ticides, and flea and tick control on pets). M O s m y be used in inert ingredients in pesticide products that are registered for specific uses that m y result in both indoor and outdoor residential exposures. A screening level residential exposure and risk assessm nt w s com leted for products containing M O s as inert ingredients. In this assessm nt, representative scenarios, based on end-use product application m thods and labeled application rates, w re selected. The M O s m y be P used as inert ingredients in pesticide form lations that are used in and around the hom . A ditionally, uses are possible in household cleaning products and in personal care products. The A ency has not selected endpoints for derm l or inhalation risk assessm nst; therefore, only exposure scenarios w ich w ll result in oral exposures have been assessed for the M O s. The A ency conducted an assessm nt to represent w rst-case residential exposure by assessing postapplication exposures and risks from M O s in pesticide form lations (outdoor scenarios) and M O s in disinfectant-type uses (indoor scenarios). Further details of this residential exposure and risk analysis can be found at *http://w regulations.gov* in the m m randum 9entitled JITF Inert Ingredients. Residential and O cupational Exposure A sessm nt A gorithm and A sum tions A pendix for the *H m n H alth Risk A sessm nts to Support Proposed Exem tion from the Requirem nt of a Tolerance When Used as Inert Ingredients in Pesticide Form lations*; (D364751, 5/7/09, Lloyd/LaM y in docket ID num er EPA H O P–2008–0710.

4. *Cum lative effects from substances w th a com n m chanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, w en considering w ether to establish, m dify, or revoke a tolerance, the A ency consider ''available inform tion'' concerning the cum lative effects of a particular pesticide's residues and ''other substances that have a com n m chanism of toxicity''.

EPA has not found M O s to share a com n m chanism of toxicity w th any other substances, and the M O s do not appear to produce a toxic m tabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assum d that the M O s do not have a com n m chanism of toxicity w th other substances. For inform tion regarding EPA s efforts to determ ne w ich chem cals have a com n m chanism of toxicity and to evaluate the cum lative effects of such chem cals, see EPA s w bsite at *http://w epa.gov/pesticides/cum lative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) m rgin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the com leteness of the database on toxicity and exposure unless EPA determ nes based on reliable data that a different m rgin of safety w ll be safe for infants and children. This additional m rgin of safety is com nly referred to as the FQ A SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF w en reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicity data available on the M O s consists of acute toxicity studies, m tagenicity studies, and an O PTS H rm nized Guideline 870.3650 com ined repeated dose toxicity study w th the reproduction developm ntal toxicity screening test.

There w s no evidence of increased sensitivity in young anim ls because no developm ntal or reproductive toxicity occurred in the low st dose group (doses of 25 m /kg/day) in the reproductive developm ntal toxicity screening test. A ditionally, no developm ntal or reproductive toxicity w s noted in the m d-dose group (doses of 50 m /kg/day); how ver, since there w re only five surviving fem le anim ls in this group, w ich is considered an insufficient num er of anim ls, the study LO L w s set at the m d-dose level. The m rtality in rats that occurred in the study w s associated w th forestom ch inflam tion. Given the extrem ly corrosive nature of the test m terial, the A ency believes that the high m rtality rate is secondary to the forestom ch lesions seen in the rats. Further, the A ency notes that the severity of the effects m y be related to the unique anatom of the rats. H m ns do not have a forestom ch w ich serves as a storage reservoir in rodents; therefore effects seen in the rat forestom ch are likely to be significantly m re severe than w at w uld be expected from the com ound in the glandular stom chs in hum ns, and therefore, have less relevance to hum ns.

There w s no evidence of neurotoxicity in the O PTS H rm nized Guideline 870.3650 study; functional-observational battery and m tor-activity data w re sim lar in all the treatm nt groups.

There are no residual uncertainties identified in the exposure databases. The dietary (food and w ter) exposure assessm nt is not likely to underestim te exposure to any subpopulation, including those com rised of infants and children.

3. *Conclusion.* EPA has determ ned that reliable data show that the safety of infants and children w uld be adequately protected if the FQ A SF w re reduced to 1X. That decision is based on the follow ng findings:

i. The toxicity database for M O s is considered adequate for assessing the risks to infants and children (the available studies are described in U it IV.D.2).

ii. N quantitative or qualitative increased susceptibility w s dem nstrated in the offspring in the O PTS H rm nized Guideline 870.3650

com ined repeated dose toxicity study w th the reproduction developm ntal toxicity screening test in rats follow ng *in utero* and post-natal exposure.

iii. A though m rtality occurred in the O PTS H rm nized Guideline 870.3650 study that w s associated w th forestom ch inflam tion, the A ency believes that, given the extrem ly corrosive nature of the test m terial, the high m rtality rate is secondary to the forestom ch lesions seen in the rats. Further, the A ency notes that the severity of the effects m y be related to the unique anatom of the rats. H m ns do not have a forestom ch w ich serves as a storage reservoir in rodents; therefore effects seen in the rat forestom ch are likely to be significantly m re severe than w at w uld be expected from the com ound in the glandular stom chs in hum ns and therefore, have less relevance to hum ns.

iv. There w s no evidence of neurotoxicity in the O PTS H rm nized Guideline 870.3650 study. Functional-observational battery and m tor-activity data w re sim lar in all the treatm nt groups. Thus, no additional neurotoxicity data are required.

v. While there is no chronic toxicity study, the A ency has concluded that since endpoint risk assessm nt is based on the forestom ch lesions in rats, a very conservative hazard endpoint, coupled w th the highly conservative exposure assessm nt and an absence of evidence of increased sensitivity, or neurotoxicity, the use of the standard 100X inter-species and intra-species U are adequate to protect infants and children, and no additional U is needed for extrapolating from subchronic to chronic exposure.

vi. There are no residual uncertainties identified in the exposure databases. The food and drinking w ter assessm nt is not likely to underestim te exposure to any subpopulation, including those com rised of infants and children. The food exposure assessm nts are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100 PCT is assum d for all crops. EPA also m de conservative (protective) assum tions in the ground and surface w ter m deling used to assess exposure to M O s in drinking w ter. EPA used sim larly conservative assum tions to assess post-application exposure of children as w ll as incidental oral exposure of toddlers. These assessm nts w ll not underestim te the exposure and risks posed by M O s.

E. A gregate Risks and Determ nation of Safety

EPA determ nes w ether acute and chronic pesticide exposures are safe by com aring aggregate exposure estim tes to the aPA and cPA . The aPA and cPA represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPA and cPA by dividing the PO by all applicable U s. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estim ted aggregate exposure. Short-term interm diate-term and chronic-term risks are evaluated by com aring the estim ted aggregate food, w ter, and residential exposure to the PO to ensure that the M called for by the product of all applicable U s is not exceeded.

1. *A ute risk.* There w s no hazard attributable to a single exposure seen in the toxicity database for M O s. Therefore, the M O s are not expected to pose an acute risk.

2. *Chronic risk.* A chronic aggregate risk assessm nt takes into account exposure estim tes from chronic dietary consum tion of food and drinking w ter. U ing the exposure assum tions discussed in this unit for chronic exposure, the chronic dietary exposure from food and w ter to M O s is 16% of the cPA for the U S. population and 51% of the cPA for children 1–2 yrs old, the m st highly exposed population subgroup.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and w ter (considered to be a background exposure level).

M O s are used as an inert ingredients in pesticide products that are currently registered for uses that could result in short-term residential exposure and the A ency has determ ned that it is appropriate to aggregate chronic exposure through food and w ter w th short-term residential exposures to M O s. U ing the exposure assum tions described in this unit, EPA has concluded the com ined short-term aggregated food, w ter, and residential exposures result in an aggregate M of 190 for children. Children's residential exposure includes hand-to-m uth exposures. A the LO is for M s that are low r than 100, this M is not of concern.

4. *Interm diate-term risk.* Interm diate-term aggregate exposure takes into account interm diate-term residential exposure plus chronic exposure to food and w ter (considered to be a background exposure level).

M O s are currently registered for uses that could result in interm diate-term residential exposure and the A ency has determ ned that it is appropriate to aggregate chronic exposure through food and w ter w th interm diate-term residential exposures to M O s. U ing the exposure assum tions described in this unit, EPA has concluded the com ined interm diate-term aggregated food, w ter, and residential exposures result in an aggregate M of 190 for children. Children's residential exposure includes hand-to-m uth exposures. A the LO is for M s that are low r than 100, this M is not of concern.

5. *A gregate cancer risk for U.S. population.* The A ency has not identified any concerns for carcinogenicity relating to M O s.

6. *Determ nation of safety.* Based on these risk assessm nts, EPA concludes that there is a reasonable certainty that no harm w ll result to the general population, or to infants and children from aggregate exposure to residues of M O s.

V. Other Considerations

A A alytical Enforcem nt M thodology

A analytical m thod is not required for enforcem nt purposes since the A ency is establishing an exem tion from the requirem nt of a tolerance w thout any num rical lim tation.

B. International Residue Lim ts

The A ency is not aw re of any country requiring a tolerance for M O s nor have any CO EX M xim m Residue Levels been established for any food crops at this tim .

VI. Conclusion

Therefore, an exem tion from the requirem nt of a tolerance is established for residues m thyl poly(oxyethylene)C_8–C_{18} alkylam nium chlorides w ere the poly(oxyethylene) content is n=2–15 and w ere C_8–C_{18} alkyl is linear and m y be saturated or unsaturated (M O s) for pre-harvest uses at a m xim m of 10% by w ight in herbicide form lations and 5% by w ight in all other form lations.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition subm tted to the A ency. The O fice of M nagem nt and Budget (O) has exem ted these types of actions from review under Executive O der 12866, entitled *Regulatory Planning and Review* (58 FR 51735,

O tober 4, 1993). Because this final rule has been exem ted from review under Executive O der 12866, this final rule is not subject to Executive O der 13211, entitled *A tions Concerning Regulations That Significantly A fect Energy Supply, Distribution, or Use* (66 FR 28355, M y 22, 2001) or Executive O der 13045, entitled *Protection of Children from Environm ntal H alth Risks and Safety Risks* (62 FR 19885, A ril 23, 1997). This final rule does not contain any inform tion collections subject to O approval under the Paperw rk Reduction A t (PRA , 44 U S.C. 3501 *et seq.*, nor does it require any special considerations under Executive O der 12898, entitled *Federal A tions to A dress Environm ntal Justice in M nority Populations and Low-Incom Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exem tions 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 requirem nts of the Regulatory Flexibility A t (RFA (5 U S.C. 601 *et seq.*) do not apply.

This final rule directly regulates grow rs, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of pow r and responsibilities established by Congress in the preem tion provisions of section 408(n)(4) of FFDCA A such, the A ency has determ ned that this action w ll not have a substantial direct effect on States or tribal governm nts, on the relationship betw en the national governm nt and the States or tribal governm nts, or on the distribution of pow r and responsibilities am ng the various levels of governm nt or betw en the Federal Governm nt and Indian tribes. Thus, the A ency has determ ned that Executive O der 13132, entitled *Federalism* (64 FR 43255, A gust 10, 1999) and Executive O der 13175, entitled *Consultation and Coordination w th Indian Tribal Governm nts* (65 FR 67249, N vem er 9, 2000) do not apply to this final rule. In addition, this final rule does not im ose any enforceable duty or contain any unfunded m ndate as described under Title II of the U funded M ndates Reform A t of 1995 (U A (Public Law 104–4).

This action does not involve any technical standards that w uld require A ency consideration of voluntary consensus standards pursuant to section 12(d) of the N tional Technology Transfer and A vancem nt A t of 1995 (N TA , Public Law 104–113, section 12(d) (15 U S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review A t, 5 U S.C. 801 *et seq.*, generally provides that before a rule m y take effect, the agency prom lgating the rule m st subm t a rule report to each H use of the Congress and to the Com troller General of the U ited States. EPA w ll subm t a report containing this rule and other required inform tion to the U S. Senate, the U S. H use of Representatives, and the Com troller General of the U ited States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''m jor rule'' as defined by 5 U S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environm ntal protection, A m nistrative practice and procedure, A ricultural com dities, Pesticides and pests, Reporting and recordkeeping requirem nts.

Dated: July 21, 2009.

G Jeffrey Herndon,

A ting Director, Registration Division, O fice of Pesticide Program .

■ Therefore, 40 CFR chapter I is am nded as follow :

PART 180—[AM NDED]

■ 1. The authority citation for part 180 continues to read as follow :

Authority: 21 U S.C. 321(q), 346a and 371.

■ 2. In §180.920, the table is am nded by adding alphabetically the follow ng inert ingredients to read as follow :

§ 180.920 nert ingredients used pre-harvest; exem tions from the requirem nt of a tolerance.

* * * * *

Inert Ingredients	Limits	ses
*		
M thyl poly(oxyethylene)C_8–C_{18} alkylam nium chlorides where he poly(oxyethylene) content is n=2–15 and where C_8–C_{18} alkyl is linear and m y be saturated or unsaturated (CAS Reg. Nos. 3010–24–0, 18448–65–2, 70750–47–9, 22340–01–8, 67784–77–4, 4755–05–1, 1791–10–4, 8724–32–5, 28880–55–9, 68187–69–9, 68607–27–2, 60687–90–3.	Concentration in form lated end use products not to exceed 10% by weight in herbicide products and 5% by weight in all other pesticide products.	Surfactants, related adjuvants of surfactants
*		

[FR Doc. E9–18348 Filed 8–4–09; 8:45 am

BILLING CO E 6560–50–S

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 180

[EPA–HQ O P–2009–0099; FRL–8428–6]

Sodium Alkyl Naphthalenesulfonate; Exem tion from the Requirem nt of a Tolerance

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Final rule.

SUM RY: This regulation establishes an exem tion from the requirem nt of a tolerance for residues of sodium alkyl naphthalenesulfonate, herein referred to in this docum nt as SA , w en used as an inert ingredient at a m xim m of 30% by w ight in pesticide form lations for pre-harvest and post-harvest uses, as w ll as, for application to anim ls. The Joint Inerts Task Force (JITF), Cluster Support Team N m er 10, subm tted a petition to EPA under the Federal Food, Drug, and Cosm tic A t (FFDCA , requesting an exem tion from the requirem nt of a tolerance. This regulation elim nates the need to establish a m xim m perm ssible level for residues of SA .

DATES: This regulation is effective A gust 5, 2009. O jections and requests for hearings m st be received on or before O tober 5, 2009, and m st be filed in accordance w th the instructions provided in 40 CFR part 178 (see also U it I.C. of the **SUPPLEM NTARY INFO M TIO).**

ADDRESSES: EPA has established a docket for this action under docket identification (ID) num er EPA H O P–2009–0099. A l docum nts in the docket are listed in the docket index

Exhibit 30

List of Subjects in 40 CFR Part 180

Environm ntal protection, A m nistrative practice and procedure, A ricultural com dities, Pesticides and pests, Reporting and recordkeeping requirem nts.

Dated: July 30, 2009.

Lois Rossi,

Director, Registration Division, O fice of Pesticide Program .

■ Therefore, 40 CFR chapter I is am nded as follow :

PART 180—[AM NDED]

■ 1. The authority citation for part 180 continues to read asfollow :

A thority: 21 U S.C. 321(q), 346a and 371.

■ 2. In § 180.920, the table is am nded by adding alphabetically the follow ng inert ingredients:

§ 180.920 nert ingredients used pre-harvest; exem tions from the requirem nt of a tolerance.

*

Inert Ingredients	im ts	ses
*		
Diethanolam ne salts of alkyl (C_8-C_{24}) benzenesulfonic acid (CAS Reg. Nos. 26545–53–9 and 68953–97–9).	Not to exceed 7% of pesticide form lation.	Surfactants, related adjuvants of surfactants
*		
Dim thylam nopropylam ne, isopropylam ne, ethanolam ne, and triethanolam ne salts of alkyl (C_8-C_{24}) benzenesulfonic acid (CAS Reg. Nos. 26264–05–1, 27323–41–7, 55470–69–4, 68411–31–4, 68584–24–7, 68584–25–8, 68648–81–7, 68648–96–4, 68649–00–3, 68910–32–7, 68953–93–5, 90194–42–6, 90194–53–9, 90218–35–2, 157966–96–6, 319926–68–6, 877677–48–0, 1093628–27–3).		Surfactants, related adjuvants of surfactants
*		

■ 3. In §180.930, the table is am nded by adding alphabetically the follow ng inert ingredients:

§ 180.930 nert ingredients applied to anim ls; exem tions from the requirem nt of a tolerance.

*

Inert Ingredients	im ts	ses
*		
Diethanolam ne salts of alkyl (C_8-C_{24}) benzenesulfonic acid (CAS Reg. Nos. 26545–53–9 and 68953–97–9).	Not to exceed 7% of pesticide form lation.	Surfactants, related adjuvants of surfactants
*		
Dim thylam nopropylam ne, isopropylam ne, ethanolam ne, and triethanolam ne salts of alkyl (C_8-C_{24}) benzenesulfonic acid (CAS Reg. Nos. 26264–05–1, 27323–41–7, 55470–69–4, 68411–31–4, 68584–24–7, 68584–25–8, 68648–81–7, 68648–96–4, 68649–00–3, 68910–32–7, 68953–93–5, 90194–42–6, 90194–53–9, 90218–35–2, 157966–96–6, 319926–68–6, 877677–48–0, 1093628–27–3).		Surfactants, related adjuvants of surfactants
*		

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BILLING CO E 6560–50–S

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 180

[EPA–HQ O P–2009–0145; FRL–8430–1]

Alkyl Alcohol Alkoxylates; Exem tion from the Requirem nt of a Tolerance

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Final rule.

SUM RY: This regulation establishes an exem tion from the requirem nt of a tolerance for [residues] of α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polym rs w ere the alkyl chain contains a m nim m of six carbons w en used as an inert ingredient in pesticide form lations. The Joint Inerts Task Force (JITF), Cluster Support Team N m er 1, subm tted a petition to EPA under the Federal Food, Drug, and Cosm tic A t (FFDCA , requesting an exem tion from the requirem nt of a tolerance. This regulation elim nates the need to establish a m xim m perm ssible level for residues of α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polym rs w ere the alkyl chain contains a m nim m of six carbons.

DATES: This regulation is effective A gust 5, 2009. O jections and requests for hearings m st be received on or before O tober 5, 2009, and m st be filed in accordance w th the instructions provided in 40 CFR part 178 (see also U it I.C. of the **SUPPLEM NTARY INFO M TIO).**

ADDRESSES: EPA has established a docket for this action under docket identification (ID) num er EPA H O P–2009–0145. A l docum nts in the docket are listed in the docket index available at *http://w regulations.gov.* A though listed in the index, som inform tion is not publicly available, e.g., Confidential Business Inform tion (CBI) or other inform tion w ose disclosure is restricted by statute. Certain other m terial, such as copyrighted m terial, is not placed on the Internet and w ll be publicly available only in hard copy form Publicly available docket m terials are available in the electronic docket at *http://w regulations.gov,* or, if only available in hard copy, at the O P Regulatory Public Docket in Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA The Docket Facility is open from 8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays. The Docket Facility telephone num er is (703) 305–5805.

FO URTHER NFO M TIO O TACT: Kerry Leifer, Registration Division (7505P), O fice of Pesticide Program ,

Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001; telephone num er: (703) 308–8811; e-m il address: leifer.kerry@*epa.gov*.

SUPPLEM NTARY NFO M TIO : I

I. General Information

A. Does this Action Apply to Me?

You m y be potentially affected by this action if you are an agricultural producer, food m nufacturer, or pesticide m nufacturer. Potentially affected entities m y include, but are not lim ted to those engaged in the follow ng activities:

- Crop production (N CS code 111).
- A im l production (N CS code 112).
- Food m nufacturing (N CS code 311).
- Pesticide m nufacturing (N CS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. O her types of entities not listed in this unit could also be affected. The N rth A rican Industrial Classification System (N CS) codes have been provided to assist you and others in determ ning w ether this action m ght apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FO URTHER INFO M TIO O TACT**.

B. How Can I Access Electronic Copies of this Docum nt?

In addition to accessing electronically available docum nts at *http:// w regulations.gov*, you m y access this **Federal Register** docum nt electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://w epa.gov/fedrgstr*. You m y also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Governm nt Printing O fice's e-CFR cite at *http://w gpoaccess.gov/ecfr*. To access the O PTS H rm nized Guidelines referenced in this docum nt, go directly to the guidelines at *http:// w epa.gpo/opptsfrs/hom / guidelin.htm*

C. Can I File an Objection or Hearing Request?

U der section 408(g) of FFDCA 21 U S.C. 346a, any person m y file an objection to any aspect of this regulation and m y also request a hearing on those objections. You m st file your objection or request a hearing on this regulation in accordance w th the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA you m st identify docket ID num er EPA H O P–2009–0145 in the subject line on the first page of your subm ssion. A l requests m st be in w iting, and m st be m iled or delivered to the H aring Clerk as required by 40 CFR part 178 on or before O tober 5, 2009.

In addition to filing an objection or hearing request w th the H aring Clerk as described in 40 CFR part 178, please subm t a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Inform tion not m rked confidential pursuant to 40 CFR part 2 m y be disclosed publicly by EPA w thout prior notice. Subm t this copy, identified by docket ID num er EPA H O P–2009–0145, by one of the follow ng m thods:

- *Federal eRulem king Portal*: *http:// w regulations.gov*. Follow the on-line instructions for subm tting com nts.
- *Mail*: O fice of Pesticide Program (O P) Regulatory Public Docket (7502P), Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001.
- *Delivery*: O P Regulatory Public Docket (7502P), Environm ntal Protection A ency, Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA Deliveries are only accepted during the Docket Facility's norm l hours of operation (8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays). Special arrangem nts should be m de for deliveries of boxed inform tion. The Docket Facility telephone num er is (703) 305–5805.

II. Background

In the **Federal Register** of A ril 15, 2009 (74 FR 17487) (FRL–8409–7), EPA issued a notice pursuant to section 408 of FFDCA 21 U S.C. 346a, announcing the receipt of a pesticide petition (PP [9E7534]) filed by The Joint Inerts Task Force, Cluster Support Team 1 (CST 1), c/o CropLife A rica, 1156 15th Street, N , Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910, 40 CFR 180.930, 40 CFR 180.940a, and 40 CFR 180.960 be am nded by establishing an exem tion from the requirem nt of a tolerance for residues of a group of substances know as α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polym rs w ere the alkyl chain contains a m nim m of 6 carbons, herein referred to in this docum nt as A A are used as inert ingredients in pesticide products. That notice referenced a sum ry of the petition prepared by The Joint Inerts Task Force (JITF), Cluster Support Team N m er 1 (CST 1)], the petitioner, w ich is available to the public in the docket, http://w regulations.gov. There w re no com nts received in response to the notice of filing.

This petition w s subm tted in response to a final rule of A gust 9, 2006, (71 FR 45415) in w ich the A ency revoked, under section 408(e)(1) of the Federal Food, Drug, and Cosm tic A t (FFDCA , the existing exem tions from the requirem nt of a tolerance for residues of certain inert ingredients because of insufficient data to m ke the determ nation of safety required by FFDCA section 408(b)(2). The expiration date for the tolerance exem tions subject to revocation w s A gust 9, 2008, w ich w s later extended to A gust 9, 2009 by a final rule published in the **Federal Register** of A gust 4, 2008 (73 FR 45312) to allow for data to be subm tted to support the establishm nt of tolerance exem tions for these inert ingredients prior to the effective date of the tolerance exem tion revocation.

Depending on the degree of alkoxylation, each of the A substances included in the petition can vary in num er average m lecular w ight from a range of approxim tely 260 to 4,000. In the case w ere the m nim m num er average m lecular w ight of an A is 1,100 or m re, the petition's basis of support for the establishm nt of an exem tion from the requirem nt of a tolerance under 40 CFR 180.960 is the fact that such high m lecular w ight A w uld m et the criteria for a low risk polym r as defined in 40 CFR 723.250. For the rem ining A (i.e., the ones w th m lecular w ights betw en 260 and 1,100), the petition seeks to establish tolerance exem tions for all A under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940(a). Therefore, in its consideration of the petition the A ency has conducted an assessm nt specific to the establishm nt of an exem tion from the requirem nt of a tolerance for the low r w ight A under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940(a) as w ll as an assessm nt specific to the establishm nt of an exem tion from the requirem nt of a tolerance under 40 CFR 180.960 for the ''high m lecular w ight'' A .

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not lim ted to, the follow ng types of ingredients (except w en they have a pesticidal efficacy of their ow): Solvents such as alcohols and

hydrocarbons; surfactants such as polyoxyethylene polym rs and fatty acids; carriers such as clay and diatom ceous earth; thickeners such as carrageenan and m dified cellulose; w tting, spreading, and dispersing agents; propellants in aerosol dispensers; m croencapsulating agents; and em lsifiers. The term "inert" is not intended to im ly nontoxicity; the ingredient m y or m y not be chem cally active. Generally, EPA has exem ted inert ingredients from the requirem nt of a tolerance based on the low toxicity of the individual inert ingredients.

IV. A gregate Risk A sessment and Determination of Safety

Section 408(b)(2)(A (i) of FFDCA allow EPA to establish an exem tion from the requirem nt of a tolerance (the legal lim t for a pesticide chem cal residue in or on a food) only if EPA determ nes that the tolerance is "safe." Section 408(b)(2)(A (ii) of FFDCA defines "safe" to m an that "there is a reasonable certainty that no harm w ll result from aggregate exposure to the pesticide chem cal residue, including all anticipated dietary exposures and all other exposures for w ich there is reliable inform tion." This includes exposure through drinking w ter and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chem cal residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm w ll result to infants and children from aggregate exposure to the pesticide chem cal residue...."

EPA perform a num er of analyses to determ ne the risks from aggregate exposure to pesticide residues. First, EPA determ nes the toxicity of pesticides. Second, EPA exam nes exposure to the pesticide through food, drinking w ter, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent w th section 408(b)(2)(D) of FFDCA and the factors specified in section 408(b)(2)(D) of FFDCA EPA has review d the available scientific data and other relevant inform tion in support of this action. EPA has sufficient data to assess the hazards of and to m ke a determ nation on aggregate exposure for the petitioned-for exem tion from the requirem nt of a tolerance for residue of A w en used as an inert ingredient in pesticide form lations applied pre- and post-harvest, applied to livestock, and used in antim crobial form lations, and as a low risk polym r as defined in 40 CFR 723.250. EPA's assessm nt of exposures and risks associated w th establishing tolerances follow .

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, com leteness, and reliability as w ll as the relationship of the results of the studies to hum n risk. EPA has also considered available inform tion concerning the variability of the sensitivities of m jor identifiable subgroups of consum rs, including infants and children.

1. *For low r w ight A s under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940a.* The available toxicology database includes acute studies, subchronic (rat and dog) studies, a m tagenicity study, three O PTS H rm nized Guideline 870.3650 com ined repeated dose toxicity studies w th the reproduction/developm ntal toxicity screening tests, an O PTS H rm nized Guideline 870.3550 reproduction/developm ntal toxicity screening test, an O PTS harm nized Test Guideline 870.3800 reproduction and fertility effects study, and reproduction and developm ntal effects studies.

The A are not acutely toxic by the oral and derm l routes of exposure under norm l use conditions. Concentrated m terials are generally m derate to severe eye and skin irritants and m y be skin sensitizers. There is no evidence of m tagenicity in the A s assay (bacterial strains).

Follow ng subchronic exposure to rats and dogs, decreases in body w ight and food consum tion w re observed, but no specific target organ toxicity or neurotoxicity w s seen. N effects w re detected in a functional observational battery (FO) or m tor activity assessm nt. In a 90–day derm l toxicity study w th A surfactant, no system c toxicity w s observed at doses up to 125 m /kg/day (the highest dose tested). In an O PTS H rm nized Guideline 870.3650 study w th the A surfactant CA N . 9004–98–2, parental toxicity observed at 110 m /kg/day included decreased absolute and relative thym s w ight, decreased body w ight gain and decreased food consum tion in fem les, and clinical signs in both sexes. These clinical signs are indicative of local irritation effects rather than system c effects and thus w re not used as a basis for evaluating the safety of the A surfactants. N reproductive or developm ntal/offspring toxicity w s observed. In the second O PTS H rm nized Guideline 870.3650 study w th the A surfactant CA 103818–93–5, parental system c toxicity w s observed at 300 m /kg/day (H T), based on decreased body w ight gain (in m les) and clinical signs (orange/red perioral staining and m derate salivation) in both sexes. N reproductive or developm ntal/offspring toxicity w s observed. In the third O PTS H rm nized Guideline 870.3650 study w th the A surfactant CA RN 64366–70–7, parental system c toxicity w s observed at 500 m /kg/day (H T), based on decreased body w ight in m les. N reproductive or developm ntal/offspring toxicity w s observed.

In an O PTS H rm nized Test Guideline 870.3550 reproduction/developm ntal toxicity screening test w th the A surfactant CA N . 84133–50–6, parental toxicity w s observed at 470 m /kg/day based on clinical signs (ptosis and hypoactivity), decreased absolute body w ight, body w ight gain, and food consum tion. Reproductive toxicity w s observed, as evidenced by the m croscopic changes in the testes and epididym des (testicular atrophy, increased intralum nal exfoliated sperm togenic cells in epididym des, and dilated sem niferous tubules). Developm ntal/offspring toxicity w s observed at 470 m /kg/day (the highest dose tested), based on decreased litter size and increased postim lantation loss.

In a reproduction and developm ntal effects study w th the A surfactant CA 68951–67–7, the only significant effects observed in fem le rats w re decreased body w ight and body w ight gain during prem ting at 400.8 m /kg/day. A this m ternally toxic dose, offspring toxicity observed w s decreased body w ight on lactation day (LD) 21 (both sexes in F_{1A}, F_{1B}, F_{2A}, and F_{2B}). N treatm nt-related effects w re observed on reproductive param ters.

In an O PTS H rm nized Test Guideline 870.3800 reproduction and fertility effects study w th A surfactant CA 68951–67–7, clinical signs observed at 250 m /kg/day w re increased incidences of lachrym tion, incidences of unkem tness, hunched posture, chrom dacryorrhea and periocular sw lling in F0 and F1 fem les. These effects m y be attributed to local irritant effects. N treatm nt-related effects w re observed on reproduction or the offspring at 250 m / kg/day (H T).

It is generally accepted that increased ethoxylation decreases lipophilicity resulting in decreased absorption and decreased toxicity. The low r m lecular w ight A w uld be expected to be absorbed and distributed m re readily than higher m lecular w ight A and

therefore to potentially be m re toxic. The representative ethoxylated com ounds tested have the low st w ight percent ethoxylation and low st m lecular w ight of the series and are potentially the m st bioavailable of the series. A though m tabolism data are not available, the m jor m tabolic pathw y for A surfactants is expected to include the hydrolysis of ether linkage to the corresponding alkyl alcohol and polyalkoxylate (PO or PO /PO) group w ich subsequently undergoes oxidative degradation and/or excretion.

There is no evidence that the A surfactants are carcinogenic. The A ency used a qualitative structure activity relationship (SA) database, DEREK Version 11, to determ ne if there w re structural alerts. N structural alerts w re identified. In addition, there w s little concern about any of the postulated m tabolites having greater toxicity than the parent com ounds.

Specific inform tion on the studies received and the nature of the adverse effects caused by A as w ll as, the no-observed-adverse-effect-level (N L) and the low st-observed-adverse-effect-level (LO L) from the toxicity studies can be found at http://w regulations.gov in docum nt A kyl A cohol A koxylates (A - JITF CST 1 Inert Ingredient). H m n H alth Risk A sessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When U ed as an Inert Ingredient in Pesticide Form lations at pp 13–20 and pp 61–75 in docket ID num er EPA H O P–2009–0145.

2. *For the high m lecular w ight A s under 40 CFR 180.960.* In the case of certain chem cal substances that are defined as polym rs, the A ency has established a set of criteria to identify categories of polym rs expected to present m nim l or no risk. The definition of a polym r is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low risk polym rs are described in 40 CFR 723.250(d). The high m lecular w ight A conform to the definition of a polym r given in 40 CFR 723.250(b) and m et the follow ng criteria that are used to identify low risk polym rs.

i. The polym r is not a cationic polym r nor is it reasonably anticipated to becom a cationic polym r in a natural aquatic environm nt.

ii. The polym r does contain as an integral part of its com osition the atom c elem nts carbon, hydrogen, and oxygen.

iii. The polym r does not contain as an integral part of its com osition, except as im urities, any elem nt other than those listed in 40 CFR 723.250(d)(2)(ii).

iv. The polym r is neither designed nor can it be reasonably anticipated to substantially degrade, decom ose, or depolym rize.

v. The polym r is m nufactured or im orted from m nom rs and/or reactants that are already included on the TSCA Chem cal Substance Inventory or m nufactured under an applicable TSCA section 5 exem tion.

vi. The polym r is not a w ter absorbing polym r w th a num er average m lecular w ight (M greater than or equal to 10,000 daltons.

A ditionally, the polym rs also m et as required the follow ng exem tion criteria specified in 40 CFR 723.250(e).

The polym r's num er average M of 1,100 daltons is greater than 1,000 and less than 10,000 daltons. The polym r contains less than 10% oligom ric m terial below M 500 and less than 25% oligom ric m terial below M 1,000, and the polym r does not contain any reactive functional groups.

Thus, the high m lecular w ight A m et the criteria for a polym r to be considered low risk under 40 CFR 723.250. Generally, polym rs of this size w uld be poorly absorbed by all routes of exposure, including through the intact gastrointestinal tract or through intact hum n skin, and therefore, no m m lian toxicity is anticipated from dietary, inhalation, or derm l exposure to the high m lecular w ight A .

B. Toxicological Endpoints

For hazards that have a threshold below w ich there is no appreciable risk, a toxicological point of departure (PO) is identified as the basis for derivation of reference values for risk assessm nt. The PO m y be defined as the highest dose at w ich no adverse effects are observed (the N L) in the toxicology study identified as appropriate for use in risk assessm nt. H w ver, if a N L cannot be determ ned, the low st dose at w ich adverse effects of concern are identified (the LO L) or a Benchm rk Dose (BM) approach is som tim s used for risk assessm nt. U certainty/safety factors (U s) are used in conjunction w th the PO to take into account uncertainties inherent in the extrapolation from laboratory anim l data to hum ns and in the variations in sensitivity am ng m m ers of the hum n population as w ll as other unknow s. Safety is assessed for acute and chronic dietary risks by com aring aggregate food and w ter exposure to the pesticide to the acute population adjusted dose (aPA) and chronic population adjusted dose (cPA). The aPA and cPA are calculated by dividing the PO by all applicable U s. A gregate short-, interm diate-, and chronic-term risks are evaluated by com aring food, w ter, and residential exposure to the PO to ensure that the m rgin of exposure (M) called for by the product of all applicable U s is not exceeded. This latter value is referred to as the Level of Concern (LO).

For non-threshold risks, the A ency assum s that any am unt of exposure w ll lead to som degree of risk. Thus, the A ency estim tes risk in term of the probability of an occurrence of the adverse effect greater than that expected in a lifetim . For m re inform tion on the general principles EPA uses in risk characterization and a com lete description of the risk assessm nt process, see *http://w epa.gov/pesticides/factsheets/riskassess.htm*

1. *For the low r w ight A s under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940a.* A sum ry of the toxicological endpoints for the A used for hum n heatlh risk assessm nt is show in the follow ng Table.

TABLE—SUM ARY TO ICOLO ICAL DOSES ND ENDPOINTS FOR THE AAAS FOR USE IN HUMAN HEALTH RISK ASSESSM NT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessm nt	Study and Toxicological Effects
Acute dietary (all populations)	o appropriate endpoint was identified for acute dietary assessm nt.		

TABLE—SUM ARY TO ICOLO ICAL DOSES ND ENDPOINTS FOR THE AAAS FOR USE IN HUMAN HEALTH RISK ASSESSM NT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessm nt	Study and Toxicological Effects
Chronic dietary (all populations)	OAEL= 168 m /kg/day UF_A = 10x UF_H = 10x FQ A SF = 1x	Chronic RfD = 1.68 m /kg/day cPAD = 1.68 m /kg/day	O PTS harm nized Test Guideline 870.3550 reproduction/developm ntal toxicity screening test MRID 47676801 (2009) LOAEL = 470 m /kg/day based on one m ternal death (GD 22), decreased body weight, body weight gain, and food consum tion, increased clinical signs (ptosis and hypoactivity), and m croscopic changes of the testes and epididym des (testicular atrophy, increased intralum nal exfoliated sperm togenic cells in epididym des, and dilated sem niferous tubules) in parental anim ls, decreased litter size, and increased postim lantation loss.
Incidental Oral and Inhalation (all durations)	NOAEL= 168 m /kg/day UF_A = 10x UF_H = 10x FQ A SF = 1x	Residential LOC for M = 100	O PTS harm nized Test Guideline 870.3550 reproduction/developm ntal toxicity screening test MRID 47676801 (2009) LOAEL = 470 m /kg/day based on one m ternal death (GD 22), decreased body weight, body weight gain, and food consum tion, increased clinical signs (ptosis and hypoactivity), and m croscopic changes of the testes and epididym des (testicular atrophy, increased intralum nal exfoliated sperm togenic cells in epididym des, and dilated sem niferous tubules) in parental anim ls, decreased litter size, and increased postim lantation loss.
Derm l (all durations)	OAEL= 168 m /kg/day UF_A = 10x UF_H = 10x FQ A SF = 1x	Residential LOC for M = 100	O PTS harm nized Test Guideline 870.3550 reproduction/developm ntal toxicity screening test MRID 47676801 (2009) Oral LOAEL = 470 m /kg/day based on one m ternal death (GD 22), decreased body weight, body weight gain, and food consum tion, increased clinical signs (ptosis and hypoactivity), and m croscopic changes of the testes and epididym des (testicular atrophy, increased intralum nal exfoliated sperm togenic cells in epididym des, and dilated sem niferous tubules) in parental anim ls, decreased litter size, and increased postim lantation loss. The final dose used to quantify derm l risk m st correct for 50% derm l absorption, and should be m ltiplied by 3 to take into account the differences in rat and hum n skin penetration. The resulting dose = 1,000 m /kg/day
Cancer (oral, derm l, inhalation)	lassification: Based on SAR analysis, AAA surfactrants are not expected to be carcinogenic.		

Point of Departure (POD) = A data point or an estim ted point that is derived from observed dose-response data and used to m rk the beginning of extrapolation to determ ne risk associated with lower environm ntally relevant hum n exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from anim l to hum n (interspecies). UF_H = potential variation in sensitivity am ng m m ers of the hum n population (intraspecies). PAD = population adjusted dose (a=acute, c=chronic). FQ A SF = FQ A Safety Factor. RfD = reference dose. M = m rgin of exposure. LOC = level of concern. N/A = not applicable.

2. *For the high m lecular w ight A s under 40 CFR 180.960.* Since the high m lecular w ight A conform to the criteria that identify a low risk polym r, and are not likely to be absorbed significantly by any route of exposure, there are no concerns for risks associated w th any potential exposure scenarios that are reasonably foreseeable. Thus, due to their low potential hazard, it w s determ ned that a quantitative risk assessm nt using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for the high m lecular w ight A , and an exposure assessm nt is not necessary. For the sam reason, an additional safety factor to protect infants and children is not needed.

C. Exposure Assessm nt

Sufficient data w re provided on the chem cal identity of the A ; how ver, lim ted data are available on the m tabolism and environm ntal degradation of these com ounds. The A ency relied collectively on inform tion provided on the representative chem cal structures, the subm tted physicochem cal data, structure-activity relationship inform tion, as w ll as inform tion on other surfactants and chem cals of sim lar size and functionality to determ ne the residues of concern for these inert ingredients. The A ency has concluded that a risk assessm nt based on toxicity data for the parent com ounds is not likely to underestim te risk.

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to the low r w ight A , EPA considered exposure under the petitioned-for exem tions from the requirem nt of a tolerance. EPA assessed dietary exposures from the low r w ight A in food as follow :

i. *Acute exposure.* N adverse effects attributable to a single exposure of the A w s seen in the toxicity databases. Therefore, acute dietary risk assessm nts for the A are not necessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessm nt, EPA used food consum tion inform tion from the U S. Departm nt of A riculture (U DA 1994–1996 and 1998 N tionw de Continuing Surveys of Food Intake by Individuals (CSFII). A to residue levels in food, no residue data w re subm tted for the A . In the absence of specific residue data, EPA has developed an approach w ich uses surrogate

inform tion to derive upper bound exposure estim tes for the subject inert ingredient. U per bound exposure estim tes are based on the highest tolerance for a given com dity from a list of high-use insecticides, herbicides, and fungicides. A com lete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the m m randum entitled *Alkyl Am nes Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessm nts for the Inerts.* (D361707, S. Piper, 2/25/09) and can be found at *http://w regulations.gov* in docket ID num er EPA H O P–2008–0738.

In the dietary exposure assessm nt, the A ency assum d that the residue level of the inert ingredient w uld be no higher than the highest tolerance for a given com dity. Im licit in this assum tion is that there w uld be sim lar rates of degradation (if any) betw en the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances w uld be no higher than the concentration of the active ingredient.

The A ency believes the assum tions used to estim te dietary exposures lead to an extrem ly conservative assessm nt of dietary risk due to a series of com ounded conservatism . First, assum ng that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient w ll overstate exposure. The concentrations of active ingredient in agricultural products is generally at least 50 percent of the product and often can be m ch higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a com ination of different inert ingredients used w ich additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this m thodology is com ounded by EPA's decision to assum that, for each com dity, the active ingredient w ich w ll serve as a guide to the potential level of inert ingredient residues is the active ingredient w th the highest tolerance level. This assum tion overstates residue values because it w uld be highly unlikely, given the high num er of inert ingredients, that a single inert ingredient or class of ingredients w uld be present at the level of the active ingredient in the highest tolerance for every com dity. Finally, a third com ounding conservatism is EPA's assum tion that all foods contain the inert ingredient at the highest tolerance level. In other w rds, EPA assum d 100 percent of all foods are treated w th the inert ingredient at the rate and m nner necessary to produce the highest residue legally possible for an active ingredient. In sum ry, EPA chose a very conservative m thod for estim ting w at level of inert residue could be on food, then used this m thodology to choose the highest possible residue that could be found on food and assum d that all food contained this residue. N consideration w s given to potential degradation betw en harvest and consum tion even though m nitoring data show that tolerance level residues are typically one to tw orders of m gnitude higher than actual residues in food w en distributed in com rce.

A cordingly, although sufficient inform tion to quantify actual residue levels in food is not available, the com ounding of these conservative assum tions w ll lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestim tes exposure in the absence of residue data.

iii. *Cancer.* The A ency used a qualitative structure activity relationship (SA) database, DEREK11, to determ ne if there w re structural alerts suggestive of carcinogenicity. N structural alerts for carcinogenicity w re identified. The A are not expected to be carcinogenic. Therefore, a cancer dietary exposure assessm nt is not necessary to assess cancer risk.

iv. *Anticipated residue and percent crop treated (PCT) inform tion.* EPA did not use anticipated residue and/or PCT inform tion in the dietary assessm nt for the A . Tolerance level residues and/or 100% CT w re assum d for all food com dities.

2. *Dietary exposure from drinking w ter.* The A ency used screening level w ter exposure m dels in the dietary exposure analysis and risk assessm nt for the A in drinking w ter. These sim lation m dels take into account data on the physical, chem cal, and fate/transport characteristics of the A . Further inform tion regarding EPA drinking w ter m dels used in the pesticide exposure assessm nt can be found at *http://w epa.gov/oppefed1/m dels/w ter/index.htm*

A screening level drinking w ter analysis, based on the Pesticide Root Zone M del /Exposure A alysis M deling System (PRZM EXA) w s perform d to calculate the estim ted drinking w ter concentrations (EDWCs) of the A . M deling runs on four surrogate inert ingredients using a range of physical chem cal properties that w uld bracket those of the A w re conducted. M deled acute drinking w ter values ranged from 0.001 ppb to 41 ppb. M deled chronic drinking w ter values ranged from 0.0002 ppb to 19 ppb. Further details of this drinking w ter analysis can be found at *http://w regulations.gov* in the docum nt *Alkyl Alcohol Alkoxylates (A - JITF CST 1 Inert Ingredient). Hum n Health Risk Assessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When Used as an Inert Ingredient in Pesticide Form lations* at pp 20–21 and 77–79 in docket ID num er EPA H O P–2009–0145.

For the purpose of the screening level dietary risk assessm nt to support this request for an exem tion from the requirem nt of a tolerance for the A , a conservative drinking w ter concentration value of 100 ppb based on screening level m deling w s used to assess the contribution to drinking w ter for chronic dietary risk assessm nts for the parent com ound. These values w re directly entered into the dietary exposure m del.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this docum nt to refer to non-occupational, non-dietary exposure (e.g., for law and garden pest control, indoor pest control, term ticides, and flea and tick control on pets). The A m y be used in inert ingredients in pesticide products that are registered for specific uses that m y result in both indoor and outdoor residential exposures. A screening level residential exposure and risk assessm nt w s com leted for products containing the A as inert ingredients. In this assessm nt, representative scenarios, based on end-use product application m thods and labeled application rates, w re selected. The A m y be used as inert ingredients in pesticide form lations that are used in and around the hom . A ditionally, these inerts m y be used in pesticide products applied to pets as aerosol sprays intended for flea control on carpeted surfaces and bedding, or in sham oo products applied to pets. Lastly, these inerts m y be present in hom cleaning products or paint products. For each of the use scenarios, the A ency assessed residential handler (applicator) inhalation and derm l exposure for use scenarios w th high exposure potential (i.e., exposure scenarios w th high-end unit exposure values) to serve as a screening assessm nt for all potential residential pesticides containing the A . Sim larly, the A ency conducted an assessm nt to represent w rst-case residential exposure by assessing post application exposures and risks from A in pesticide form lations

(outdoor scenarios), A in disinfectant-type uses (indoor scenarios), A in sham oo pet treatm nts (pet product scenarios) and A in paint products (paint product scenarios). Further details of this residential exposure and risk analysis can be found at *http://w regulations.gov* in the m m randum entitled *JITF Inert Ingredients Residential and O cupational Exposure Assessm nt Algorithm and Assum tions Appendix for the Hum n Health Risk Assessm nts to Support Proposed Exem tion from the Requirem nt of a Tolerance When Used as Inert Ingredients in Pesticide Form lations* (D364751, 5/7/09, Lloyd/LaM y in docket ID num er EPA H O P–2008–0710.

4. *Cum lative effects from substances w th a com n m chanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, w en considering w ether to establish, m dify, or revoke a tolerance, the A ency consider ''available inform tion'' concerning the cum lative effects of a particular pesticide's residues and ''other substances that have a com n m chanism of toxicity.''

EPA has not found A to share a com n m chanism of toxicity w th any other substances, and the A do not appear to produce a toxic m tabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assum d that the A do not have a com n m chanism of toxicity w th other substances. For inform tion regarding EPA's efforts to determ ne w ich chem cals have a com n m chanism of toxicity and to evaluate the cum lative effects of such chem cals, see EPA's w bsite at *http://w epa.gov/pesticides/cum lative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) m rgin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the com leteness of the database on toxicity and exposure unless EPA determ nes based on reliable data that a different m rgin of safety w ll be safe for infants and children. This additional m rgin of safety is com nly referred to as the FQ A safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor w en reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the case of the low r w ight A surfactants, there w s no evidence of increased susceptibility to the offspring of rats follow ng prenatal and postnatal exposure in the reproductive/developm ntal screening studies on several representative A surfactants. Decreased litter size and increased postim lantation loss w re observed in one O PTS H rm nized Guideline 870.3550 reproduction/developm ntal toxicity screening study at 470 m /kg/day w ere m ternal/paternal toxicity w s m nifested as one m ternal death (GD 22), decreased body w ight, body-w ight gain and food consum tion and clinical signs (ptosis and hypoactivity) and m croscopic changes in the testes (atrophy) and epididym des (increased intralum nal exfoliated sperm togenic cells) and dilated sem niferous tubules at the sam dose (470 m /kg/day). The m ternal and offspring toxicity N L w s 168 m /kg/day. The offspring toxicity in the O PTS H rm nized Test Guideline 870.3650 study w s m nifested in the presence of m re severe m ternal toxicity (deaths), therefore, EPA concluded that there is no evidence of increased susceptibility in this study. In addition, there w s no evidence of increased susceptibility in other subm tted studies.

3. *Conclusion.* EPA has determ ned that reliable data show that the safety of infants and children w uld be adequately protected if the FQ A SF w re reduced to 1X for the low r w ight A . (A discussed earlier, given the low toxicological concerns w th the high w ight A , a safety factor analysis is unnecessary). That decision as to the low r w ight A is based on the follow ng findings:

i. The toxicity database for the A is considered adequate for assessing the risks to infants and children. The toxicity database consists of three O PTS H rm nized Test Guideline 870.3650 com ined repeated dose toxicity studies w th the reproduction/developm ntal toxicity screening tests, an O PTS H rm nized Test Guidelinge 870.3550 reproduction/developm ntal toxicity screening test study, an O PTS H rm nized Test Guideline 870.3800 reproduction and fertility effects study, and reproduction and developm ntal effects studies. The A ency noted changes in thym s w ight. H w ver, the thym s/lym h node effects are considered secondary effects caused by an overall stress response to the irritant properties of this chem cal, and therefore, not an im nological response. In addition, no blood param ters w re affected in the database. Furtherm re, these com ounds do not belong to a class of chem cals that w uld be expected to be im notoxic. A so, in an O PTS H rm nized Test Guideline 870.3550 study, testicular effects, such as, testicular atrophy, m croscopic changes in the testes, epididym des and dilated sem niferous tubules w re observed in m le rats at the highest dose tested (470 m /kg/day). H w ver, none of the reproductive param ters (pregnancy rate) w re affected in this study. In addition, there w re no effects observed on reproductive param ters in the O PTS H rm nized Test Guideline 870.3800 reproduction and fertility effects study. Furtherm re, there w s no histological findings in the testes in that study. Based on the w ight of the evidence for im notoxoicity and reproductive toxicity, there is no need to add additional uncertainty factors.

ii. EPA concluded that there is no evidence of qualitative or quantitative increased susceptivility in the available database. Therefore, there is no concern for increased susceptibility to infants and children.

iii. There is no indication that the A are neurotoxic chem cals and thus there is no need for a developm ntal neurotoxicity study or additional U s to account for neurotoxicity

iv. A though the chronic point of departure w s selected from a subchronic study, longer-term studies are available that support the N L selected. N additional uncertainty factor is needed for extrapolating from subchronic to chronic exposure.

v. There are no residual uncertainties identified in the exposure databases. The food and drinking w ter assessm nt is not likely to underestim te exposure to any subpopulation, including those com rised of infants and children. The food exposure assessm nts are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100% crop treated is assum d for all crops. EPA also m de conservative (protective) assum tions in the ground and surface w ter m deling used to assess exposure to the A in drinking w ter. EPA used sim larly conservative assum tions to assess post-application exposure of children as w ll as incidental oral exposure of toddlers. These assessm nts w ll not underestim te the exposure and risks posed by the A .

E. Aggregate Risks and Determ nation of Safety

1. *For the low r w ight A s under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940a.* EPA determ nes w ether

acute and chronic pesticide exposures are safe by com aring aggregate exposure estim tes to the aPA and cPA . The aPA and cPA represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPA and cPA by dividing the PO by all applicable U s. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estim ted aggregate exposure. Short-, interm diate-, and chronic-term risks are evaluated by com aring the estim ted aggregate food, w ter, and residential exposure to the PO to ensure that the M called for by the product of all applicable U s is not exceeded.

i. *Acute risk.* There w s no hazard attributable to a single exposure seen in the toxicity database for the A . Therefore, the A are not expected to pose an acute risk.

ii. *Chronic risk.* A chronic aggregate risk assessm nt takes into account exposure estim tes from chronic dietary consum tion of food and drinking w ter. U ing the exposure assum tions discussed in this unit for chronic exposure the chronic dietary exposure from food and w ter to the A is 11% of the cPA for the U S. population and 37% of the cPA for children 1 to 2 years old, the m st highly exposed population subgroup.

iii. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and w ter (considered to be a background exposure level).

A are used as inert ingredients in pesticide products that are currently registered for uses that could result in short-term residential exposure and the A ency has determ ned that it is appropriate to aggregate chronic exposure through food and w ter w th short-term residential exposures to the A . EPA has concluded that the com ined short-term aggregated food, w ter, and residential exposures result in aggregate M s of 110 for both adult m les and fem les. A ult residential exposure com ines high end indoor inhalation handler exposure w th a high-end post application to pet exposures. EPA has concluded the com ined short-term aggregated food, w ter, and residential exposures result in an aggregate M of 110 for children. Children's residential exposure includes total com ined pet exposures. A the level of concern is for M s that are low r than 100, these M s are not of concern.

iv. *Interm diate-term risk.* Interm diate-term aggregate exposure takes into account interm diate-term residential exposure plus chronic exposure to food and w ter (considered to be a background exposure level).

The A are used as inert ingredients in pesticide products that are currently registered for uses that could result in interm diate-term residential exposure and the A ency has determ ned that it is appropriate to aggregate chronic exposure through food and w ter w th interm diate-term residential exposures to the A . EPA has concluded that the com ined interm diate-term aggregated food, w ter, and residential exposures result in aggregate M s of 230 for both adult m les and fem les, respectively. A ult residential exposure includes high-end post application derm l exposure from contact w th treated pets. EPA has concluded that the com ined interm diate-term aggregated food, w ter, and residential exposures result in an aggregate M of 110 for children. Children's residential exposure includes total com ined pet exposure. A the level of concern is for M s that are low r than 100, these M s are not of concern.

v. *Aggregate cancer risk for U.S. population.* The A ency has not identified any concerns for carcinogenicity relating to the A .

vi. *Determ nation of safety.* Based on these risk assessm nts, EPA concludes that there is a reasonable certainty that no harm w ll result to the general population or to infants and children from aggregate exposure to residues of the low r w ight A .

2. *For the high m lecular w ight A s under 40 CFR 180.960.* Since A conform to the criteria that identify a low risk polym r, there are no concerns for risks associated w th any potential exposure scenarios that are reasonably foreseeable. Therefore, EPA concludes that there is a reasonable certainty that no harm w ll result to the general population or to infants and children from aggregate exposure to residues of the high m lecular w ight A .

V. Other Considerations

A. Analytical Enforcem nt Methodology

A analytical m thod is not required for enforcem nt purposes since the A ency is establishing an exem tion from the requirem nt of a tolerance w thout any num rical lim tation.

B. International Residue Lim ts

The A ency is not aw re of any country requiring a tolerance for the A nor have any CO EX M xim m Residue Levels been established for any food crops at this tim .

VI. Conclusion

Therefore, an exem tion from the requirem nt of a tolerance is established for residues of the low r m lecular w ight α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polym rs w ere the alkyl chain contains a m nim m of 6 carbons w en used as an inert ingredient in pesticide form lations applied pre- and post-harvest, applied to livestock, and used in antim crobial form lations under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940(a). In addition, an exem tion from the requirem nt of a tolerance is established for residues of the larger m lecular w ight com ounds of α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polym rs w ere the alkyl chain contains a m nim m of 6 carbons under 40 CFR 180.960.

VII. Statutory and Executive Order Reviews

This final rule establishes an exem tion from the requirem nt of tolerances under section 408(d) of FFDCA in response to a petition subm tted to the A ency. The O fice of M nagem nt and Budget (O) has exem ted these types of actions from review under Executive O der 12866, entitled *Regulatory Planning and Review* (58 FR 51735, O tober 4, 1993). Because this final rule has been exem ted from review under Executive O der 12866, this final rule is not subject to Executive O der 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, M y 22, 2001) or Executive O der 13045, entitled *Protection of Children from Environm ntal Health Risks and Safety Risks* (62 FR 19885, A ril 23, 1997). This final rule does not contain any inform tion collections subject to O approval under the Paperw rk Reduction A t (PRA , 44 U S.C. 3501 *et seq .*, nor does it require any special considerations under Executive O der 12898, entitled *Federal Actions to Address Environm ntal Justice in Minority Populations and Low-Incom Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates grow rs, food processors, food handlers, and food retailers, not States or tribes,

nor does this action alter the relationships or distribution of pow r and responsibilities established by Congress in the preem tion provisions of section 408(n)(4) of FFDCA A such, the A ency has determ ned that this action w ll not have a substantial direct effect on States or tribal governm nts, on the relationship betw en the national governm nt and the States or tribal governm nts, or on the distribution of pow r and responsibilities am ng the various levels of governm nt or betw en the Federal Governm nt and Indian tribes. Thus, the A ency has determ ned that Executive O der 13132, entitled *Federalism* (64 FR 43255, A gust 10, 1999) and Executive O der 13175, entitled *Consultation and Coordination w th Indian Tribal Governm nts* (65 FR 67249, N vem er 9, 2000) do not apply to this final rule. In addition, this final rule does not im ose any enforceable duty or contain any unfunded m ndate as described under Title II of the U funded M ndates Reform A t of 1995 (U A (Public Law 104–4).

This action does not involve any technical standards that w uld require A ency consideration of voluntary consensus standards pursuant to section 12(d) of the N tional Technology Transfer and A vancem nt A t of 1995 (N TA , Public Law 104–113, section 12(d) (15 U S.C. 272 note).

VIII. Congressional Review A t

The Congressional Review A t, 5 U S.C. 801 *et seq.*, generally provides that before a rule m y take effect, the agency prom lgating the rule m st subm t a rule report to each H use of the Congress and to the Com troller General of the U ited States. EPA w ll subm t a report containing this rule and other required inform tion to the U S. Senate, the U S. H use of Representatives, and the Com troller General of the U ited States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''m jor rule'' as defined by 5 U S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environm ntal protection, A m nistrative practice and procedure, A ricultural com dities, Pesticides and pests, Reporting and recordkeeping requirem nts.

Dated: July 29, 2009.

Lois Rossi,

Director, Registration Division, O fice of Pesticide Program .

■ Therefore, 40 CFR chapter I is am nded as follow :

PART 180—[AM NDED]

■ 1. The authority citation for part 180 continues to read as follow :

A thority: 21 U S.C. 321(q), 346a and 371.

■ 2. In § 180.910, the table is am nded by adding alphabetically the follow ng inert ingredients:

§ 180.910 nert ingredients used pre- and post-harvest; exem tions from the requirem nt of a tolerance.

*

Inert ingredients	im ts	ses
*		
α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polym rs where the alkyl chain contains a m nim m of six carbons (CAS Reg. Nos. 9002–92–0, 9004–95–9, 9005–00–9, 6183–52–8, 4398–01–1, 2 2292–17–8, 3 6455–14–9, 5 6455–15–0, 6 68002–97–1, 8131–39–5, 8131–40–8, 8154–96–1, 8213–23–0, 8439–45–2, 68439–46–3, 8526–94–3, 8439–50–9, 8439–49–6, 8551–12–2, 8951–67–7, 71243–46–4, 7043–91–9, 043–30–5, 9 0828–78–6, 9 1827–42–7, 6 4938–91–8, 6 68439–54–3, 69011–36–5, 78330–20–8, 78330–21–9, 106232–83–1, 127036–24–2, 160875–66–1, 004–98–2, 8920–66–1, 1804–34–0, 1791–28–4, 1060–57–6, 26468–86–0, 1726–34–8, 2609–19–5, 1791–20–6, 8155–01–1, 9013–19–0, 69364–63–2, 0879–83–3, 8330–19–5, 7953–22–5, 57627–86–6, 4398–05–5, 72905–87–4, 4133–50–6, 1702–78–1, 7306–79–2, 69107–21–5, 1791–13–7, 39587–22–9, 5422–93–1; 8154–98–3, 1725–89–1, 8002–96–0, 8154–97–2, 68439–51–0, 8551–13–3, 8603–25–8, 8937–66–6, 8987–81–5, 9227–21–0, 70750–27–5, 103818–93–5, 166736–08–9, 120313–48–6, 68213–24–1, 68458–88–8, 68551–14–4, 9013–18–9, 9227–22–1, 2854–13–8, 3049–34–0, 8330–23–1, 37311–02–7, 4366–70–7, 7251–67–5, 087–53–0, 96823–11–7, 7679–21–7, 111905–54–5, 61827–84–7, 172588–43–1)		Surfactants, elated djuvants f surfactants 6 2
*		

■ 3. In §180.930, the table is am nded by adding alphabetically the follow ng inert ingredients:

§ 180.930 nert ingredients applied to anim ls; exem tions from the requirem nt of a tolerance.

*

Inert Ingredients	im ts	ses
*		
α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polym rs where the alkyl chain contains a m nim m of six carbons (CAS Reg. Nos. 9002–92–0, 9004–95–9, 9005–00–9, 26183–52–8, 34398–01–1, 52292–17–8, 66455–14–9, 66455–15–0, 68002–97–1, 68131–39–5, 68131–40–8, 68154–96–1, 68213–23–0, 68439–45–2, 68439–46–3, 68526–94–3, 68439–50–9, 68439–49–6, 68551–12–2, 68951–67–7, 71243–46–4, 97043–91–9, 9043–30–5, 60828–78–6, 61827–42–7, 24938–91–8, 68439–54–3, 69011–36–5, 78330–20–8, 78330–21–9, 106232–83–1, 127036–24–2, 160875–66–1, 9004–98–2, 68920–66–1, 61804–34–0, 61791–28–4, 71060–57–6, 26468–86–0, 31726–34–8, 52609–19–5, 61791–20–6, 68155–01–1, 69013–19–0, 69364–63–2, 70879–83–3, 78330–19–5, 97953–22–5, 157627–86–6, 4398–05–53 2905–87–47 4133–50–68 1702–78–16 7306–79–22 169107–21–5, 1791–13–76 9587–22–93 5422–93–18 8154–98–36 1725–89–16 68002–96–0, 68154–97–2, 68439–51–0, 68551–13–3, 68603–25–8, 68937–66–6, 68987–81–5, 69227–21–0, 70750–27–5, 103818–93–5, 166736–08–9, 120313–48–6, 68213–24–1, 8458–88–8, 8551–14–4, 9013–18–9, 9227–22–1, 2854–13–8, 3049–34–0, 78330–23–1, 37311–02–7, 64366–70–7, 37251–67–5, 9087–53–0, 196823–11–7, 57679–21–7, 111905–54–5, 61827–84–7, 172588–43–1)		Surfactants, elated djuvants f surfactants
*		

■ 4. Section §180.940 is am nded by alphabetically adding the follow ng entry to the table in paragraph (a):

§ 180.940 olerance exem tions for active and inert ingredients for use in antim crobial form lations (Food-contact surface sanitizing solutions).

(a) *

*

Pesticide Chem cal	AS Reg. No.	im ts
*		
α-alkyl-ω-hydroxypoly oxypropylene) nd/or poly (oxyethylene) polym rs where the alkyl chain contains a m nim m of six carbons.	9002–92–0, 004–95–9, 005–00–9, 6183–52–8, 4398–01–1, 52292–17–8, 66455–14–9, 66455–15–0, 68002–97–1, 68131–39–5, 8131–40–8, 8154–96–1, 8213–23–0, 8439–45–2, 68439–46–3, 68526–94–3, 68439–50–9, 68439–49–6, 68551–12–2, 8951–67–7, 1243–46–4, 7043–91–9, 043–30–5, 60828–78–6, 61827–42–7, 24938–91–8, 68439–54–3, 69011–36–5, 78330–20–8, 78330–21–9, 106232–83–1, 127036–24–2, 160875–66–1, 9004–98–2, 68920–66–1, 61804–34–0, 61791–28–4, 1060–57–6, 6468–86–0, 1726–34–8, 2609–19–5, 61791–20–6, 68155–01–1, 69013–19–0, 69364–63–2, 70879–83–3, 8330–19–5, 7953–22–5, 57627–86–6, 4398–05–5, 72905–87–4, 84133–50–6, 61702–78–1, 27306–79–2, 169107–21–5, 1791–13–7, 9587–22–9, 5422–93–1; 8154–98–3, 61725–89–1, 68002–96–0, 68154–97–2, 68439–51–0, 68551–13–3, 8603–25–8, 8937–66–6, 8987–81–5, 9227–21–0, 70750–27–5, 03818–93–5, 66736–08–9, 20313–48–6, 68213–24–1, 68458–88–8, 68551–14–4, 69013–18–9, 69227–22–1, 2854–13–8, 3049–34–0, 8330–23–1, 7311–02–7, 64366–70–7, 37251–67–5, 9087–53–0, 196823–11–7, 57679–21–7, 111905–54–5, 61827–84–7, 172588–43–1)	
*		

■ 5. In §180.960, the table is am nded by adding alphabetically the follow ng polym rs:

§ 180.960 olym rs; exem tions from the requirem nt of a tolerance.

*

Polym r	AS No.
*	
α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) poly-m rs where the alkyl chain contains a m n-im m of six carbons, m nim m num er aver-age m lecular weight (in am) 1,100.	9002–92–0, 9004–95–9, 9005–00–9, 26183–52–8, 34398–01–1, 52292–17–8, 66455–14–9, 66455–15–0, 68002–97–1, 68131–39–5, 68131–40–8, 68154–96–1, 68213–23–0, 68439–45–2, 68439–46–3, 68526–94–3, 68439–50–9, 68439–49–6, 68551–12–2, 68951–67–7, 71243–46–4, 97043–91–9, 9043–30–5, 60828–78–6, 61827–42–7, 24938–91–8, 68439–54–3, 69011–36–5, 78330–20–8, 78330–21–9, 106232–83–1, 127036–24–2, 160875–66–1, 9004–98–2, 68920–66–1, 61804–34–0, 61791–28–4, 71060–57–6, 26468–86–0, 31726–34–8, 52609–19–5, 61791–20–6, 68155–01–1, 69013–19–0, 69364–63–2, 70879–83–3, 78330–19–5, 97953–22–5, 157627–86–6, 34398–05–5, 72905–87–4, 84133–50–6, 61702–78–1, 27306–79–2, 169107–21–5, 61791–13–7, 39587–22–9, 85422–93–1; 68154–98–3, 61725–89–1, 68002–96–0, 68154–97–2, 68439–51–0, 68551–13–3, 68603–25–8, 68937–66–6, 68987–81–5, 69227–21–0, 70750–27–5, 103818–93–5, 166736–08–9, 120313–48–6, 68213–24–1, 68458–88–8, 68551–14–4, 69013–18–9, 69227–22–1, 72854–13–8, 73049–34–0, 78330–23–1, 37311–02–7, 64366–70–7, 37251–67–5, 9087–53–0, 196823–11–7, 57679–21–7, 111905–54–5, 61827–84–7, 172588–43–1
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[FR Doc. E9–18706 Filed 8–4–09; 8:45 am
BILLING CO E 6560–50–S

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 180

[EPA–HQ O P–2008–0944; FRL–8429–4]

Polyoxyethylene polyoxypropylene m no(di-sec-butylphenyl) ether; Exem tion from the Requirem nt of a Tolerance

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Final rule.

SUM RY: This regulation establishes an exem tion from the requirem nt of a tolerance for residues of Polyoxyethylene polyoxypropylene m no(di-sec-butylphenyl) ether w en used as an inert ingredient in herbicide form lations only, for pre-harvest uses and at no m re than 30% by w ight in herbicide form lations intended for application to turf. The Joint Inerts Task Force (JITF), Cluster Support Team N m er 20, subm tted a petition to EPA under the Federal Food, Drug, and Cosm tic A t (FFDCA , requesting an exem tion from the requirem nt of a tolerance. This regulation elim nates the need to establish a m xim m perm ssible level for residues of Polyoxyethylene polyoxypropylene m no(di-sec-butylphenyl) ether.

DATES: This regulation is effective A gust 5, 2009. O jections and requests for hearings m st be received on or before O tober 5, 2009, and m st be filed in accordance w th the instructions provided in 40 CFR part 178 (see also U it I.C. of the **SUPPLEM NTARY INFO M TIO).**

ADDRESSES: EPA has established a docket for this action under docket identification (ID) num er EPA H O P–2008–0944. A l docum nts in the docket are listed in the docket index available at *http://w regulations.gov*. A though listed in the index, som a inform tion is not publicly available, e.g., Confidential Business Inform tion (CBI) or other inform tion w ose disclosure is restricted by statute. Certain other m terial, such as copyrighted m terial, is not placed on the Internet and w ll be publicly available only in hard copy form Publicly available docket m terials are available in the electronic docket at *http://w regulations.gov*, or, if only available in hard copy, at the O P Regulatory Public Docket in Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA The Docket Facility is open from 8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays. The Docket Facility telephone num er is (703) 305–5805.

FO URTHER NFO M TIO O TACT: Kerry Leifer, Registration Division (7505P), O fice of Pesticide Program , Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001; telephone num er: (703) 308–8811; e-m il address: leifer.kerry@*epa.gov*.

SUPPLEM NTARY NFO M TIO : I

I. General Information

A. Does this Action Apply to Me?

You m y be potentially affected by this action if you are an agricultural producer, food m nufacturer, or pesticide m nufacturer. Potentially affected entities m y include, but are not lim ted to those engaged in the follow ng activities:

- Crop production (N CS code 111).
- A im l production (N CS code 112).
- Food m nufacturing (N CS code 311).
- Pesticide m nufacturing (N CS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. O her types of entities not listed in this unit could also be affected. The N rth A rican Industrial Classification System (N CS) codes have been provided to assist you and others in determ ning w ether this action m ght apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FO URTHER INFO M TIO O TACT.**

B. How Can I Access Electronic Copies of this Docum nt?

In addition to accessing electronically available docum nts at *http://w regulations.gov*, you m y access this **Federal Register** docum nt electronically through the EPA Internet under the "**Federal Register**" listings at *http://w epa.gov/fedrgstr*. You m y also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Governm nt Printing O fice's e–CFR cite at *http://w gpoaccess.gov/ecfr*. To access the O PTS H rm nized Guidelines referenced in this docum nt, go directly to the guidelines at *http://w epa.gpo/opptsfrs/hom / guidelin.htm*

C. Can I File an Objection or Hearing Request?

U der section 408(g) of FFDCA 21 U S.C. 346a, any person m y file an objection to any aspect of this regulation and m y also request a hearing on those objections. You m st file your objection or request a hearing on this regulation in accordance w th the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA you m st identify docket ID num er EPA H O P–2008–0944 in the subject line on the first page of your subm ssion. A l requests m st be in w iting, and m st be m iled or delivered to the H aring Clerk as required by 40 CFR part 178 on or before O tober 5, 2009.

In addition to filing an objection or hearing request w th the H aring Clerk as described in 40 CFR part 178, please subm t a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES.** Inform tion not m rked confidential pursuant to 40 CFR part 2 m y be disclosed publicly by EPA w thout prior notice. Subm t this copy, identified by docket ID num er EPA H O P–2008–0944, by one of the follow ng m thods:

- *Federal eRulem king Portal*: *http://w regulations.gov*. Follow the on-line instructions for subm tting com nts.
- *Mail*: O fice of Pesticide Program (O P) Regulatory Public Docket (7502P), Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001.
- *Delivery*: O P Regulatory Public Docket (7502P), Environm ntal Protection A ency, Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA Deliveries are only accepted during the Docket Facility's norm l hours of operation (8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays). Special arrangem nts should be m de for deliveries of boxed inform tion. The Docket Facility telephone num er is (703) 305–5805.

II. Background

In the **Federal Register** of M rch 25, 2009 (74 FR 12856) (FRL–8399–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA 21 U S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7494) by The Joint Inerts Task Force (JITF), Cluster Support Team 20 (CST 20), c/o CropLife A rica, 1156 15th Street, N , Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.920 be am nded by establishing exem tions from the requirem nt of a tolerance for residues of the inert ingredient

Exhibit 31

Express M il Contract 3 (M 2009–15 and CP2009–21)
Express M il Contract 4 (M 2009–34 and CP2009–45)
Express M il & Priority M il Contract 1 (M 2009–6 and CP2009–7)
Express M il & Priority M il Contract 2 (M 2009–12 and CP2009–14)
Express M il & Priority M il Contract 3 (M 2009–13 and CP2009–17)
Express M il & Priority M il Contract 4 (M 2009–17 and CP2009–24)
Express M il & Priority M il Contract 5 (M 2009–18 and CP2009–25)
Express M il & Priority M il Contract 6 (M 2009–31 and CP2009–42)
Express M il & Priority M il Contract 7 (M 2009–32 and CP2009–43)
Express M il & Priority M il Contract 8 (M 2009–33 and CP2009–44)
Parcel Select & Parcel Return Service Contract 2 (M 2009–40 and CP2009–61)
Parcel Return Service Contract 1 (M 2009–1 and CP2009–2)
Priority M il Contract 1 (M 2008–8 and CP2008–26)
Priority M il Contract 2 (M 2009–2 and CP2009–3)
Priority M il Contract 3 (M 2009–4 and CP2009–5)
Priority M il Contract 4 (M 2009–5 and CP2009–6)
Priority M il Contract 5 (M 2009–21 and CP2009–26)
Priority M il Contract 6 (M 2009–25 and CP2009–30)
Priority M il Contract 7 (M 2009–25 and CP2009–31)
Priority M il Contract 8 (M 2009–25 and CP2009–32)
Priority M il Contract 9 (M 2009–25 and CP2009–33)
Priority M il Contract 10 (M 2009–25 and CP2009–34)
Priority M il Contract 11 (M 2009–27 and CP2009–37)
Priority M il Contract 12 (M 2009–28 and CP2009–38)
Priority M il Contract 13 (M 2009–29 and CP2009–39)
Priority M il Contract 14 (M 2009–30 and CP2009–40)
Priority M il Contract 15 (M 2009–35 and CP2009–54)
Priority M il Contract 16 (M 2009–36 and CP2009–55)
Priority M il Contract 17 (M 2009–37 and CP2009–56)
Priority M il Contract 18 (M 2009–42 and CP2009–63)
O tbound International
Direct Entry Parcels Contracts
Direct Entry Parcels 1 (M 2009–26 and CP2009–36)
Global Direct Contracts (M 2009–9, CP2009–10, and CP2009–11)
Global Expedited Package Services (GEPS) Contracts
GEPS 1 (CP2008–5, CP2008–11, CP2008–12, and CP2008–13,
CP2008–18, CP2008–19, CP2008–20, CP2008–21, CP2008–22, CP2008–23, and CP2008–24)
Global Expedited Package Services 2 (CP2009–50)
Global Plus Contracts
Global Plus 1 (CP2008–8, CP2008–46 and CP2009–47)
Global Plus 2 (M 2008–7, CP2008–48 and CP2008–49)
Inbound International
Inbound Direct Entry Contracts w th Foreign Postal A m nistrations
Inbound Direct Entry Contracts w th Foreign Postal A m nistrations (M 2008–6, CP2008–14 and M 2008–15)
Inbound Direct Entry Contracts w th Foreign Postal A m nistrations 1 (M 2008–6 and CP2009–62)
International Business Reply Service Com etitive Contract 1 (M 2009–14 and CP2009–20)
Com etitive Product Descriptions
Express M il
[Reserved for Group Description]
Express M il
[Reserved for Product Description]
O tbound International Expedited Services
[Reserved for Product Description]
Inbound International Expedited Services
[Reserved for Product Description]
Priority
[Reserved for Product Description]
Priority M il
[Reserved for Product Description]
O tbound Priority M il International
[Reserved for Product Description]
Inbound A r Parcel Post
[Reserved for Product Description]
Parcel Select
[Reserved for Group Description]
Parcel Return Service
[Reserved for Group Description]
International
[Reserved for Group Description]
International Priority A rlift (IPA
[Reserved for Product Description]
International Surface A rlift (ISA)
[Reserved for Product Description]
International Direct Sacks—M–Bags
[Reserved for Product Description]
Global Custom zed Shipping Services
[Reserved for Product Description]
International M ney Transfer Service
[Reserved for Product Description]
Inbound Surface Parcel Post (at non-U U rates)
[Reserved for Product Description]
International A cillary Services
[Reserved for Product Description]
International Certificate of M iling
[Reserved for Product Description]
International Registered M il
[Reserved for Product Description]
International Return Receipt
[Reserved for Product Description]
International Restricted Delivery
[Reserved for Product Description]
International Insurance
[Reserved for Product Description]
N gotiated Service A reem nts
[Reserved for Group Description]
Dom stic
[Reserved for Product Description]
O tbound International
[Reserved for Group Description]
Part C—Glossary of Term and Conditions [Reserved]
Part D—Country Price Lists for International M il [Reserved]

[FR Doc. E9–24237 Filed 10–6–09; 8:45 am
BILLING CO E 7710–FW P

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 180

[EPA–HQ O P–2009–0490; FRL–8439–1]

Sodium and Am nium Naphthalenesulfonate Form ldehyde Condensates; Exem tion from the Requirem nt of a Tolerance

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Final rule.

SUM RY: This regulation establishes an exem tion from the requirem nt of a tolerance for residues of the sodium and am nium napthalenesulfonate form ldehyde condensates, herein referred to in this docum nt as the SA Cs, w en used as inert ingredients in pesticide form lations applied pre-harvest and post-harvest. The Joint Inerts Task Force (JITF), Cluster Support Team N m er 11 and A zo N bel Surface Chem stry, LLC, subm tted petitions to EPA under the Federal Food, Drug, and Cosm tic A t (FFDCA , requesting an exem tion from the requirem nt of a tolerance. This regulation elim nates the need to establish a m xim m perm ssible level for residues of the SA Cs.

DATES: This regulation is effective O tober 7, 2009. O jections and requests for hearings m st be received on or before Decem er 7, 2009, and m st be filed in accordance w th the instructions provided in 40 CFR part 178 (see also U it I.C. of the **SUPPLEM NTARY NFO M TIO). I**

ADDRESSES: EPA has established a docket for this action under docket identification (ID) num er EPA H O P–2009–0490. A l docum nts in the docket are listed in the docket index available at *http://w regulations.gov.* A though listed in the index, som inform tion is not publicly available, e.g., Confidential Business Inform tion (CBI) or other inform tion w ose disclosure is restricted by statute. Certain other m terial, such as copyrighted m terial, is not placed on the Internet and w ll be publicly available only in hard copy form Publicly available docket m terials are available in the electronic docket at *http://w regulations.gov*, or, if only

available in hard copy, at the O P Regulatory Public Docket in Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA The Docket Facility is open from 8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays. The Docket Facility telephone num er is (703) 305–5805.

FO URTHER NFO M TIO O TACT: Elizabeth Fertich, Registration Division (7505P), O fice of Pesticide Program , Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001; telephone num er: (703) 347–8560; e-m il address: *fertich.elizabeth@epa.gov.*

SUPPLEM NTARY NFO M TIO : I

I. G neral Inform tion

A Does this A tion A ply to M ?

You m y be potentially affected by this action if you are an agricultural producer, food m nufacturer, or pesticide m nufacturer. Potentially affected entities m y include, but are not lim ted to those engaged in the follow ng activities:

- Crop production (N CS code 111).
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C. Can I File an O jection or H aring Request?

U der section 408(g) of FFDCA 21 U S.C. 346a, any person m y file an objection to any aspect of this regulation and m y also request a hearing on those objections. You m st file your objection or request a hearing on this regulation in accordance w th the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA you m st identify docket ID num er EPA H O P–2009–0490 in the subject line on the first page of your subm ssion. A l requests m st be in w iting, and m st be m iled or delivered to the H aring Clerk as required by 40 CFR part 178 on or before Decem er 7, 2009.

In addition to filing an objection or hearing request w th the H aring Clerk as described in 40 CFR part 178, please subm t a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Inform tion not m rked confidential pursuant to 40 CFR part 2 m y be disclosed publicly by EPA w thout prior notice. Subm t this copy, identified by docket ID num er EPA H O P–2009–0490, by one of the follow ng m thods:

- *Federal eRulem king Portal*: *http:// w regulations.gov*. Follow the on-line instructions for subm tting com nts.
- *M il*: O fice of Pesticide Program (O P) Regulatory Public Docket (7502P), Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001.
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II. Background

In the **Federal Register** of A gust 19, 2009 (74 FR 41898) (FRL–8426–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA 21 U S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7572) by The JITF, CST 11, c/o CropLife A rica, 1156 15th Street, N , Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910 be am nded by establishing exem tions from the requirem nt of a tolerance for residues of SA Cs. That notice referenced a sum ry of the petition prepared by the JITF, CST 11, the petitioner, w ich is available to the public in the docket, *http:// w regulations.gov.* Docket ID num er EPA H O P–2009–0043 w s established for this petition. There w re no com nts received in response to the notice of filing.

In the **Federal Register** of A gust 19, 2009 (74 FR 41895]) (FRL–8429–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA 21 U S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7562) by A zo N bel Surface Chem stry, LLC, 525 West Van Buren Street, Chicago, IL 60607–3823. The petition requested that 40 CFR 180.910 be am nded by establishing exem tions from the requirem nt of a tolerance for residues of m no-, di-, and trim thylnapthalenesulfonic acids and napthalenesulfonic acids form ldehyde condensates, am nium and sodium salts. That notice referenced a sum ry of the petition prepared by A zo N bel Surface Chem stry, LLC, the petitioner, w ich is available to the public in the docket, *http://w regulations.gov.* Docket ID num er EPA H O P–2008–0822 w s established for this petition. There w re no com nts received in response to the notice of filing.

These tw petitions are grouped because they fall under the sam general chem cal description criteria.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not lim ted to, the follow ng types of ingredients (except w en they have a pesticidal efficacy of their ow): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polym rs and fatty acids; carriers such as clay and diatom ceous earth; thickeners such as carrageenan and m dified cellulose; w tting, spreading, and dispersing agents; propellants in aerosol dispensers; m croencapsulating agents; and em lsifiers. The term ''inert'' is not intended to im ly nontoxicity; the ingredient m y or m y not be chem cally active. Generally, EPA has exem ted inert ingredients from the requirem nt of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessm nt and Determ nation of Safety

Section 408(b)(2)(A (i) of FFDCA allow EPA to establish an exem tion from the requirem nt of a tolerance (the

legal lim t for a pesticide chem cal residue in or on a food) only if EPA determ nes that the tolerance is ''safe.'' Section 408(b)(2)(A (ii) of FFDCA defines ''safe'' to m an that ''there is a reasonable certainty that no harm w ll result from aggregate exposure to the pesticide chem cal residue, including all anticipated dietary exposures and all other exposures for w ich there is reliable inform tion.'' This includes exposure through drinking w ter and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chem cal residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm w ll result to infants and children from aggregate exposure to the pesticide chem cal residue. . . .''

EPA perform a num er of analyses to determ ne the risks from aggregate exposure to pesticide residues. First, EPA determ nes the toxicity of pesticides. Second, EPA exam nes exposure to the pesticide through food, drinking w ter, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent w th section 408(b)(2)(D) of FFDCA and the factors specified in section 408(b)(2)(D) of FFDCA EPA has review d the available scientific data and other relevant inform tion in support of this action. EPA has sufficient data to assess the hazards of and to m ke a determ nation on aggregate exposure for the petitioned-for exem tion from the requirem nt of a tolerance for residues of the SA Cs w en used as inert ingredients in pesticide form lations applied pre-harvest and post-harvest. EPA s assessm nt of exposures and risks associated w th establishing tolerances follow .

A Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, com leteness, and reliability as w ll as the relationship of the results of the studies to hum n risk. EPA has also considered available inform tion concerning the variability of the sensitivities of m jor identifiable subgroups of consum rs, including infants and children.

The toxicology database for the SA C inerts is adequate to support their use as inert ingredients in pesticide form lations. The existing toxicology database for the SA C consists of tw O PTS H rm nized Guidelines 870.3650 (com ined repeated dose toxicity study w th the reproduction/developm ntal toxicity screening test in rats), and several studies from the scientific literature on acute toxicity and m tagenicity.

The available toxicity data indicates that SA C has low acute oral and inhalation toxicity. SA C w s not m tagenic in an A s test. In a repeated 28 to 42 day O PTS H rm nized Guideline 870.3650 com ined repeated dose toxicity study w th the reproduction/developm ntal toxicity screening w th the representative test com ound, naphthalenesulfonic acid, sodium salt polym r w th form ldehyde (CA 9084–06–4), there w s no evidence of increased susceptibility. Parental toxicity m nifested as decrem nts in body-w ight gain in both sexes at the lim t dose (1,000 m lligram /kilogram day (m /kg/day). N developm ntal or reproductive effects w re observed at doses of 100, 300, and 1,000 m /kg/day. In an O PTS H rm nized Guideline 870.3650 study subm tted by A zo N bel Chem stry, LLC, no system c toxicity w s observed at doses up to and including 456 m /kg/day. The highest dose tested (H T). There w s no evidence of potential neurotoxicity or im notoxicity in the adult anim l in the O PTS H rm nized Guideline 870.3650 study at the lim t dose of 1,000 m /kg/day. There is no evidence that the SA Cs are carcinogenic. There are no chronic data available on the SA C surfactants; how ver, no structural alerts for cancer w re identified in a qualitative structure activity relationship (SA) database, DEREK Version 11. In addition, there w s little concern about any of the postulated m tabolites having greater toxicity than the parent com ounds. The higher m lecular w ight (M polym ric SA C surfactants (M >1,000) are not expected to be readily absorbed or m tabolized, and should thus be rapidly excreted (likely in the feces) unchanged. A ditionally, low r m lecular m crosom cytochrom P-450 oxygenases m y hydroxylate the naphthalene ring and/or m thylene bridge to produce alternative m tabolites that should also be readily conjugated and excreted. Furtherm re, these com ounds are form ldehyde condensates and do not contain free form ldehyde. Therefore, form ldehyde is not a residue of concern. In sum ry, all available data indicate that SA Cs have a low hazard potential.

Specific inform tion on the studies received are included in the A ency's H m n H alth Risk A sessm nt w ich can be found at *http://w regulations.gov* in docum nt *Sodium and A nium Naphthalenesulfonate Form ldehyde Condensates (SANFCs) - JITF CST 11 Inert Ingredients), H m n H alth Risk A sessm nt to Support Proposed Exem tion from the Requirem nt of a Tolerance When Used as Inert Ingredients in Pesticide Form lations,* pages 6–8 and 11–14 in docket ID num er EPA H O P–2009–0043 and also in docum nt *M no-, Di-, and Trim thylnapthalensulfonic A ids and Naphthalenesulfonic A ids Form ldehyde Condensates, A nium and Sodium Salts: Review of Toxicological Studies in Support of an Exem tion from the Requirem nt of a Tolerance (40 CFR 180.920 and 40 CFR 180.910) When Used as Inert Ingredients in Pesticide Form lations* in docket ID num er EPA H O P–2008–0822.

B. Toxicity Endpoint Selection and FQPA Considerations

There w s no significant hazard identified in the O PTS H rm nized Guideline 870.3650 study at the lim t dose of 1,000 m /kg/day to either parental anim ls or their offspring. Thus, due to their low potential hazard and the lack of a hazard endpoint, it w s determ ned that a quantitative risk assessm nt using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for the SA Cs. The A ency notes that there w s no evidence of neurotoxicity or increased susceptibility to the offspring of rats follow ng prenatal or postnatal exposure in the O PTS H rm nized Guideline 870.3650 studies. Based on this inform tion, there is no concern, at this tim , for increased sensitivity to infants and children to the SA Cs w en used as inert ingredients in pesticide form lations applied pre-harvest and post-harvest and a safety factor analysis has not been used to assess risk. For the sam reason, EPA has determ ned that an additional safety factor is not needed to protect the safety of infants and children.

C. A gregate Exposures

In exam ning aggregate exposure, section 408 of FFDCA directs EPA to consider available inform tion concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking w ter from ground w ter or surface w ter and exposure through pesticide use in gardens, law s, or buildings (residential and other indoor uses).

The SA C inerts are used as disperants, defoam rs and em lsifiers in pesticide form lations. These surfactants have a w de range of

industrial uses as w ll as serving as em lsifiers in personal care products and in food contact packaging.

The residues of concern are the parent com ound only. Considering the large size and polarity of the SA C m lecules, it is unlikely that they w uld be readily absorbed by livestock or taken up by plants for further m tabolism

N hazard w s identified for the acute and chronic dietary assessm nt (food and drinking w ter), or for the short-term interm diate-term and long-term residential assessm nts, and therefore, no quantitative aggregate exposure assessm nts w re perform d.

D. Cum lative Effects From Substances With a Com n M chanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, w en considering w ether to establish, m dify, or revoke a tolerance, the A ency consider "available inform tion" concerning the cum lative effects of a particular pesticide's residues and "other substances that have a com n m chanism of toxicity."

EPA has not found the SA Cs to share a com n m chanism of toxicity w th any other substances, and SA Cs do not appear to produce a toxic m tabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assum d that SA Cs do not have a com n m chanism of toxicity w th other substances. For inform tion regarding EPA s efforts to determ ne w ich chem cals have a com n m chanism of toxicity and to evaluate the cum lative effects of such chem cals, see EPA s w bsite at *http://w epa.gov/pesticides/cum lative.*

E. Determ nation of safety

Based on all available inform tion, EPA concludes that there is a reasonable certainty that no harm w ll result to the general population or to infants and children from aggregate exposure to residues of the SA Cs w en used as inert ingredients in pesticide form lations applied pre-harvest and post-harvest.

V. Other Considerations

A A alytical Enforcem nt M thodology

A analytical m thod is not required for enforcem nt purposes since the A ency is establishing an exem tion from the requirem nt of a tolerance w thout any num rical lim tation.

B. Existing Exem tions

The SA Cs have an existing exem tion from the requirem nt of a tolerance under 40 CFR 180.920 for use as inert ingredients in pesticide form lations applied to grow ng crops.

C. International Residue Lim ts

The A ency is not aw re of any country requiring a tolerance for the SA Cs nor have any CO EX M xim m Residue Levels been established for any food crops at this tim .

VI. Conclusion

Therefore, an exem tion from the requirem nt of a tolerance is established for residues of the SA Cs, under the tolerance expression m no-, di-, and trim thylnapthalenesulfonic acids and napthalenesulfonic acids form ldehyde condensates, am nium and sodium salts, w en used as inert ingredients in pesticide form lations applied pre-harvest and post-harvest.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition subm tted to the A ency. The O fice of M nagem nt and Budget (O) has exem ted these types of actions from review under Executive O der 12866, entitled *Regulatory Planning and Review* (58 FR 51735, O tober 4, 1993). Because this final rule has been exem ted from review under Executive O der 12866, this final rule is not subject to Executive O der 13211, entitled *A tions Concerning Regulations That Significantly A fect Energy Supply, Distribution, or Use* (66 FR 28355, M y 22, 2001) or Executive O der 13045, entitled *Protection of Children from Environm ntal H alth Risks and Safety Risks* (62 FR 19885, A ril 23, 1997). This final rule does not contain any inform tion collections subject to O approval under the Paperw rk Reduction A t (PRA , 44 U S.C. 3501 *et seq.*, nor does it require any special considerations under Executive O der 12898, entitled *Federal A tions to A dress Environm ntal Justice in M nority Populations and Low-Incom Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates grow rs, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of pow r and responsibilities established by Congress in the preem tion provisions of section 408(n)(4) of FFDCA A such, the A ency has determ ned that this action w ll not have a substantial direct effect on States or tribal governm nts, on the relationship betw en the national governm nt and the States or tribal governm nts, or on the distribution of pow r and responsibilities am ng the various levels of governm nt or betw en the Federal Governm nt and Indian tribes. Thus, the A ency has determ ned that Executive O der 13132, entitled *Federalism* (64 FR 43255, A gust 10, 1999) and Executive O der 13175, entitled *Consultation and Coordination w th Indian Tribal Governm nts* (65 FR 67249, N vem er 9, 2000) do not apply to this final rule. In addition, this final rule does not im ose any enforceable duty or contain any unfunded m ndate as described under Title II of the U funded M ndates Reform A t of 1995 (U A (Public Law 104–4).

This action does not involve any technical standards that w uld require A ency consideration of voluntary consensus standards pursuant to section 12(d) of the N tional Technology Transfer and A vancem nt A t of 1995 (N TA , Public Law 104–113, section 12(d) (15 U S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review A t, 5 U S.C. 801 *et seq.*, generally provides that before a rule m y take effect, the agency prom lgating the rule m st subm t a rule report to each H use of the Congress and to the Com troller General of the U ited States. EPA w ll subm t a report containing this rule and other required inform tion to the U S. Senate, the U S. H use of Representatives, and the Com troller General of the U ited States prior to publication of this final rule in the **Federal Register**. This final rule is not a "m jor rule" as defined by 5 U S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environm ntal protection, A m nistrative practice and procedure, A ricultural com dities, Pesticides and pests, Reporting and recordkeeping requirem nts.

Dated: Septem er 30, 2009.

G Jeffrey Herndon,

A ting Director, Registration Division, O fice of Pesticide Program .

■ Therefore, 40 CFR chapter I is am nded as follow :

PART 180—[AM NDED]

■ 1. The authority citation for part 180 continues to read as follow :

Authority: 21 U S.C. 321(q), 346a and 371.

■ 2. In §180.910, the table is am nded by adding alphabetically the follow ng inert ingredients to read as follow :

§ 180.910 nert ingredients used pre- and post-harvest; exem tions from the requirem nt of a tolerance.

* * * * *

Inert Ingredients	im ts	ses
*		
M no-, di-, and trim thylnapthalenesulfonic acids and napthalenesulfonic acids form ldehyde condensates, am nium and sodium salts (CAS Reg. Nos 008–63–3, 069–80–1, 084–06–4, 6290–04–7, 1078–68–1, 141959–43–5, 68425–94–5)		Surfactants, related adjuvants of surfactants
*		

[FR Doc. E9–24160 Filed 10–6–09; 8:45 am

BILLING CO E 6560–50–S

ENVIRO M NTAL PRO ECTIO AG NCY

40 CFR Part 180

[EPA–HQ O P–2009–0690; FRL–8437–3]

C_{10}-C_{18}-Alkyl dim thyl am ne oxides; Exem tion from the Requirem nt of a Tolerance

AG NCY: Environm ntal Protection A ency (EPA .

ACTIO : Final rule.

SUM RY: This regulation establishes an exem tion from the requirem nt of a tolerance for residues of C_{10}-C_{18}-A kyl dim thyl am ne oxides (A A w en used as the inert ingredient in pesticide form lations applied to raw agricultural com dities pre- and post-harvest. Exponent on behalf of Stepan Com any and Rhodia subm tted petitions to EPA under the Federal Food, Drug, and Cosm tic A t (FFDCA , requesting an exem tion from the requirem nt of a tolerance. This regulation elim nates the need to establish a m xim m perm ssible level for residues of A A .

DATES: This regulation is effective O tober 7, 2009. O jections and requests for hearings m st be received on or before Decem er 7, 2009, and m st be filed in accordance w th the instructions provided in 40 CFR part 178 (see also U it I.C. of the **SUPPLEM NTARY NFO M TIO).** I

ADDRESSES: EPA has established a docket for this action under docket identification (ID) num er EPA H O P–2009–0690. A l docum nts in the dockets are listed in the docket index available at *http://w regulations.gov*. A though listed in the index, som inform tion is not publicly available, e.g., Confidential Business Inform tion (CBI) or other inform tion w ose disclosure is restricted by statute. Certain other m terial, such as copyrighted m terial, is not placed on the Internet and w ll be publicly available only in hard copy form Publicly available docket m terials are available in the electronic docket at *http://w regulations.gov*, or, if only available in hard copy, at the O P Regulatory Public Docket in Rm S–4400, O e Potom c Yard (South Bldg.), 2777 S. Crystal Dr., A lington, VA The Docket Facility is open from 8:30 a.m to 4 p.m , M nday through Friday, excluding legal holidays. The Docket Facility telephone num er is (703) 305–5805.

FO URTHER NFO M TIO O TACT: Lisa A stin, Registration Division (7505P), O fice of Pesticide Program , Environm ntal Protection A ency, 1200 Pennsylvania A e., N , Washington, DC 20460–0001; telephone num er: (703) 305–7894; e-m il address: *austin.lisa@epa.gov*.

SUPPLEM NTARY NFO M TIO : I

I. G neral Inform tion

A Does this A tion A ply to M ?

You m y be potentially affected by this action if you are an agricultural producer, food m nufacturer, or pesticide m nufacturer. Potentially affected entities m y include, but are not lim ted to:

- Crop production (N CS code 111).
- A im l production (N CS code 112).
- Food m nufacturing (N CS code 311).
- Pesticide m nufacturing (N CS 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. O her types of entities not listed in this unit could also be affected. The N rth A rican Industrial Classification System (N CS) codes have been provided to assist you and others in determ ning w ether this action m ght apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FO URTHER INFO M TIO O TACT.**

B. H w Can I A cess Electronic Copies of this Docum nt?

In addition to accessing electronically available docum nts at *http://w regulations.gov*, you m y access this **Federal Register** docum nt electronically through the EPA Internet under the "**Federal Register**" listings at *http://w epa.gov/fedrgstr*. You m y also access a frequently updated electronic version of 40 CFR part 180 through the Governm nt Printing O fice's e-CFR cite at *http://w gpoaccess.gov/ecfr*. To access the O PTS H rm nized Guidelines referenced in this docum nt, go to the guidelines at *http://w epa.gov/opptsfrs/hom /guidelin.htm*

C. Can I File an O jection or H aring Request?

U der section 408(g) of FFDCA 21 U S.C. 346a, any person m y file an objection to any aspect of this regulation and m y also request a hearing on those objections. The EPA procedural regulations w ich govern the subm ssion of objections and requests for hearings appear in 40 CFR part 178. You m st file your objection or request a hearing on this regulation in accordance w th the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA you m st identify docket ID num er EPA H O P–2009–0690 in the subject line on the first page of your subm ssion. A l requests m st be in w iting, and m st be m iled or delivered to the H aring Clerk on or before Decem er 7, 2009.

In addition to filing an objection or hearing request w th the H aring Clerk as described in 40 CFR part 178, please subm t a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES.** Inform tion not m rked confidential pursuant to 40 CFR part 2 m y be disclosed publicly by EPA w thout prior notice. Subm t your copies, identified by docket ID num er

Exhibit 32

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Delores Barber, attest that I am the Director of the Information Technology and Resources Management Division (ITRMD) of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

Document Dated: May 1, 2013
Federal Register, Glyphosate; Pesticide Tolerances Final Rule (13 pages)

Subscribed under the penalty of perjury on this 7th day of June, 2018.

Delores Barber

Delores Barber, Director
Information Technology and Resources Management Division (ITRMD)

CERTIFICATION OF TRUE COPY

I, Wendy Blake, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

Wendy L. Blake
Associate General Counsel
General Law Office
Office of General Counsel

Date: 6/11/18

LEGAL STATUS

LEGAL STATUS

Glyphosate; Pesticide Tolerances

A Rule by the Environmental Protection Agency on 05/01/2013

DOCUMENT DETAILS

Printed version:
PDF (https://www.gpo.gov/fdsys/pkg/FR-2013-05-01/pdf/2013-10316.pdf)

Publication Date:
05/01/2013 (/documents/2013/05/01)

Agency:
Environmental Protection Agency (https://www.federalregister.gov/agencies/environmental-protection-agency)

Dates:
This regulation is effective May 1, 2013. Objections and requests for hearings must be received on or before July 1, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (/select-citation/2018/06/18/40-CFR-178) (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

Effective Date:
05/01/2013

Document Type:
Rule

Document Citation:
78 FR 25396

Page:
25396-25401 (6 pages)

CFR:
40 CFR 180

Agency/Docket Numbers:
EPA-HQ-OPP-2012-0132
FRL-9384-3

Document Number:
2013-10316

DOCUMENT DETAILS

ENHANCED CONTENT

regulations.gov

Docket Number:
EPA-HQ-OPP-2012-0132 (https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0132)

Supporting/Related Materials:
Drinking Water Assessment for Label Amendments (Roundup... (https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0132-0013)
Glyphosate. Section 3 Registration Concerning the Application... (https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0132-0012)
Glyphosate. Dietary Exposure and Risk Assessment in Support of... (https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0132-0011)
Glyphosate. Section 3 Registration Concerning the Application... (https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0132-0010)
Notice of Filing for Glyphosate on the root and tuber... (https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0132-0005)

ENHANCED CONTENT

PUBLISHED DOCUMENT

AGENCY:

Environmental Protection Agency (EPA).

ACTION:

Final rule.

SUMMARY:

This regulation establishes tolerances for residues of glyphosate in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES:

This regulation is effective May 1, 2013. Objections and requests for hearings must be received on or before July 1, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (/select-citation/2013/05/01/40-CFR-178) (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES:

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0132, is available at *http://www.regulations.gov (http://www.regulations.gov)* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets (http://www.epa.gov/dockets).*

FOR FURTHER INFORMATION CONTACT:

Andrew Ertman, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; email address: *ertman.andrew@epa.gov (mailto:ertman.andrew@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 (/select-citation/2013/05/01/40-CFR-180) through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl (http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).*

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

Under FFDCA section 408(g), 21 U.S.C. 346 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=346&type=usc&link-type=html)a, 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 (/select-citation/2013/05/01/40-CFR-178). To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0132 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 July 1, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25 (/select-citation/2013/05/01/40-CFR-178.25)(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178 (/select-citation/2013/05/01/40-CFR-178), please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 (/select-citation/2013/05/01/40-CFR-2) may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0132, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov (http://www.regulations.gov).* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html (http://www.epa.gov/dockets/contacts.html).*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets (http://www.epa.gov/dockets).*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 2, 2012 (77 FR 25954 (/citation/77-FR-25954)) (FRL-9346-1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=346&type=usc&link-type=html)a(d)(3), announcing the filing of a pesticide petition (PP 2E7979) by IR-4, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.364 (/select-citation/2013/05/01/40-CFR-180.364) be amended by establishing tolerances for residues of the herbicide glyphosate *N*-(phosphonomethyl) glycine in

or on the raw agricultural commodity teff, forage and teff, hay at 100 parts per million (ppm) and oilseed crops, group 20 at 40 ppm. The petition also requested amendments to the tolerances in 40 CFR 180.364 (/select-citation/2013/05/01/40-CFR-180.364) as follows: Vegetable, root and tuber, group 1, except sugar beet, from 0.2 ppm to 6.0 ppm; vegetable, bulb, group 3 at 0.2 ppm to vegetable, bulb, group 3-07 at 0.2 ppm; okra at 0.5 ppm; vegetable, fruiting, group 8 at 0.1 ppm to vegetable, fruiting, group 8-10 at 0.1 ppm; fruit, citrus, group 10 at 0.5 ppm to fruit, citrus, group 10-10 at 0.5 ppm; fruit, pome, group 11 at 0.2 ppm to fruit, pome, group 11-10 at 0.2 ppm; cranberry, grape, juneberry, kiwifruit, lingonberry, salal, strawberry, and berry group 13 at 0.2 ppm to berry and small fruit, group 13-07 at 0.2 ppm. That document referenced a summary of the petition prepared by Monsanto, the registrant, which is available in the docket at *http://www.regulations.gov (http://www.regulations.gov)*. There were no comments received in response to the notice of filing.

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Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for some commodities as well as the crops for which tolerances are being established. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for glyphosate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with glyphosate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A chronic feeding/carcinogenicity study in rats found no systemic effects in any of the parameters examined (body weight, food consumption, clinical signs, mortality, clinical pathology, organ weights, and histopathology). A second chronic feeding/carcinogenicity study in rats tested at higher dietary levels, and a lowest-observed-adverse-effect level (LOAEL) was identified at 20,000 ppm (approximately 940 milligram/kilogram/day (mg/kg/day)) based on decreased body-weight gains in females and increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight, and increased relative liver weight/brain weight in males. No evidence of carcinogenicity was found in mice or rats. In a chronic toxicity study in dogs, no systemic effects were found in all examined parameters.

There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in developmental studies. A focal tubular dilation of the kidneys was observed in an older 3-generation reproductive study on rats at the 30-mg/kg/day level (highest dose tested (HDT)); however, a 2-generation reproductive study on rats did not observe the same effect at the 1,500 mg/kg/day level (HDT), nor were any adverse reproductive effects observed at any dose level. A clear NOAEL was established and the chronic reference dose (cRfD) was set at a level well below this effect. Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental, or reproductive studies performed with glyphosate.

Neurotoxicity screening battery tests and an immunotoxicity study have been submitted to the Agency. Given the timing of the submission of these studies, the Agency has conducted preliminary reviews of these studies. The preliminary reviews show no effects up to the HDT for both the acute and subchronic durations for the neurotoxicity studies and no effects up to the HDT in the immunotoxicity study. EPA does not believe that further review will result in different conclusions concerning the neurotoxic or immunotoxic potential of glyphosate.

Specific information on the studies received and the nature of the adverse effects caused by glyphosate as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov (http://www.regulations.gov)* in the document entitled "Glyphosate. Section 3 Registration Concerning the Application of Glyphosate to Carrots, Sweet Potato, Teff, and Oilseeds (Crop Group (CG) 20) and to Update the CG Definitions for Bulb Vegetable (CG 3-07), Fruiting Vegetable (CG 8-10), Citrus Fruit (CG 10-10), Pome Fruit (CG 11-10), and Berry (CG 13-07). Human-Health Risk Assessment" on pp. 26-28 in docket ID number EPA-HQ-OPP-2012-0132.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a RfD—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm (http://www.epa.gov/pesticides/factsheets/riskassess.htm).*

A summary of the toxicological endpoints for glyphosate used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 8, 2011 (76 FR 19701 (/citation/76-FR-19701)) (FRL-8866-8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to glyphosate, EPA considered exposure under the petitioned-for tolerances as well as all existing glyphosate tolerances in 40 CFR 180.364 (/select-citation/2013/05/01/40-CFR-180.364). EPA assessed dietary exposures from glyphosate in food as follows:

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i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

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

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for both proposed and existing commodities.

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

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

2. *Dietary exposure from drinking water.* The Agency used both a screening level water exposure model (surface water) as well as monitoring data (ground water) in the dietary exposure analysis and risk assessment for glyphosate in drinking water. The simulation model takes into account data on the physical, chemical, and fate/transport characteristics of glyphosate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm (http://www.epa.gov/oppefed1/models/water/index.htm).*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and monitoring data from the National Water-Quality Assessment Program (NAWQA), the estimated drinking water concentrations (EDWCs) of glyphosate for chronic exposures are estimated to be 8.11 parts per billion (ppb) for surface water and 2.03 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 8.11 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Glyphosate is currently registered for the following uses that could result in residential exposures: Turf (including golf courses and residential lawns) and for aquatic application. EPA assessed residential exposure using the following assumptions:

Based on the registered residential use patterns, there is a potential for short-term dermal and inhalation exposures to homeowners who mix and apply products containing glyphosate (residential handlers). However, since short- and intermediate-term dermal or inhalation endpoints were not selected, a

quantitative exposure risk assessment was not completed.

Based on the registered use patterns, children 1-2 years old may have short-term post-application incidental oral exposures from hand-to-mouth behavior on treated lawns and swimmers (adults and children 3-6 years old) may have short-term post-application incidental oral exposures from aquatic uses. Based on the soil half-life for glyphosate, intermediate-term soil ingestion was also considered for children 1<2 years old. The incidental oral scenarios for the turf assessment (i.e., hand-to-mouth, object-to-mouth, and soil ingestion) should be considered inter-related and it is likely that they occur interspersed amongst each other across time. Combining these scenarios would be overly conservative because of the conservative nature of each individual assessment. Therefore, none of the incidental oral scenarios were combined.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf (http://www.epa.gov/pesticides/trac/science/trac6a05.pdf).*

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

EPA has not found glyphosate to share a common mechanism of toxicity with any other substances, and glyphosate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that glyphosate 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 (http://www.epa.gov/pesticides/cumulative).*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in developmental studies. A focal tubular dilation of the kidneys was observed in an older 3-generation reproductive study on rats at the 30-mg/kg/day level (HDT); however, a 2-generation reproductive study on rats did not observe the same effect at the 1,500 mg/kg/day level (HDT), nor were any adverse reproductive effects observed at any dose level. A clear NOAEL was established and the cRfD was set at a level well below this effect. Therefore, the endpoints selected for risk assessment are protective of the effects seen in the 3-generation rat reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for glyphosate is complete.

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ii. There is no indication that glyphosate is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. As discussed in Unit III.D.2., there is no evidence that glyphosate results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies.

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

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to glyphosate from food and water will utilize 13% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of glyphosate is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Glyphosate is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to glyphosate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,000 for the general U.S. population and 450 for children 1-2 years old. Because EPA's level of concern for glyphosate is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Glyphosate is currently registered for uses that could result in intermediate-term residential exposure to children 1-2 years old, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to glyphosate.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 770 for children 1-2 years old, the population subgroup of concern. Because EPA's level of concern for glyphosate is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, glyphosate is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to glyphosate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC)) 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; email address: *residuemethods@epa.gov (mailto:residuemethods@epa.gov).*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint 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 established MRLs for glyphosate in or on cotton seed at 40 ppm, sunflower seed at 7 ppm, and rape seed at 20 ppm. The MRL for cotton seed is the same as the oilseed crop group tolerance and the MRL for rape seed is the same as the canola seed tolerance being established by this document. Based on the oilseed residue data, harmonization with the Codex sunflower seed tolerance is not possible.

C. Revisions to Petitioned-For Tolerances

The Agency has revised the petitioned-for tolerances as follows:

The proposed increase in tolerance for vegetables, root and tuber, group 1, except sugar beet from 0.2 ppm to 6 ppm cannot be done at this time due to inadequate residue data. Instead, the Agency is establishing individual tolerances for carrot at 5.0 ppm and sweet potato at 3.0 ppm and modifying the existing tolerance on vegetables, root and tuber, group 1, except sugar beet at 0.20 ppm to read as "vegetables, root and tuber, group 1, except sugar beet, carrot, and sweet potato."

The petition requested a tolerance at 40 ppm on the oilseed group 20. In order to maintain harmonization with both Canada and Codex the Agency is establishing a tolerance on the oilseed crop group 20, except canola at 40 ppm and is maintaining the existing canola seed tolerance at 20 ppm.

The petition requested that the current tolerance for vegetable, fruiting, group 8 be updated to the new vegetable, fruiting, group 8-10. Okra is part of the new crop group, however, and the currently established tolerance in or on crop group 8 is 0.1 ppm, whereas the okra tolerance is 0.5 ppm. Due to this difference, the Agency is updating crop group 8 to read "vegetable, fruiting, group 8-10, except okra" and maintaining the existing okra tolerance at 0.5 ppm.

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Lastly, several of the tolerance values on the crop group conversions are being revised to reflect Agency policy concerning significant figures.

V. Conclusion

Therefore, tolerances are established for residues of glyphosate *N*-(phosphonomethyl) glycine in or on the raw agricultural commodity teff, forage at 100 ppm; teff, hay at 100 ppm; oilseeds, group 20, except canola at 40 ppm; vegetable, root and tuber, group 1, except carrot, sweet potato, and sugar beet at 0.20 ppm; carrot at 5.0 ppm; sweet potato at 3.0 ppm; vegetable, bulb, group 3-07 at 0.20 ppm; vegetable, fruiting, group 8-10 (except okra) at 0.10 ppm; fruit, citrus, group 10-10 at 0.50 ppm; fruit, pome, group 11-10 at 0.20 ppm; and berry and small fruit, group 13-07 at 0.20 ppm.

In addition, due to the establishment of the tolerances in this document, the following tolerances are being removed as unnecessary: Vegetables, root and tuber, crop group 1, except sugar beet; vegetable, bulb, group 3; vegetable, fruiting, group 8; fruit, citrus, group 10; fruit, pome, group 11; berry group 13; borage, seed; cotton, undelinted seed; crambe, seed; flax, meal; flax, seed; jojoba seed; lesquerella, seed; meadowfoam, seed; mustard seed; rapeseed, seed; safflower, seed; sesame, seed; sunflower, seed; cranberry; grape; juneberry; kiwifruit; lingonberry; salal; and strawberry.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) 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, (/executive-order/13211) entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (/citation/66-FR-28355), May 22, 2001) or Executive Order 13045, (/executive-order/13045) entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885 (/citation/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 (https://api.fdsys.gov/link?collection=uscode&title=44&year=mostrecent&section=3501&type=usc&link-type=html) *et seq.*), nor does it require any special considerations under Executive Order 12898, (/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 FFDCA section 408(d), 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 (https://api.fdsys.gov/link?

collection=uscode&title=5&year=mostrecent&section=601&type=usc&link-type=html) *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 FFDCA section 408(n)(4). 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, (/executive-order/13132) entitled "Federalism" (64 FR 43255 (/citation/64-FR-43255), August 10, 1999) and Executive Order 13175, (/executive-order/13175) entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249 (/citation/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) (2 U.S.C. 1501 (https://api.fdsys.gov/link?collection=uscode&title=2&year=mostrecent&section=1501&type=usc&link-type=html) *et seq.*).

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) (15 U.S.C. 272 (https://api.fdsys.gov/link?collection=uscode&title=15&year=mostrecent&section=272&type=usc&link-type=html) note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 (https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=801&type=usc&link-type=html) *et seq.*), 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 the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804 (https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=804&type=usc&link-type=html)(2).

List of Subjects in 40 CFR Part 180 (/select-citation/2013/05/01/40-CFR-180)

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

Dated: April 19, 2013.

Daniel J. Rosenblatt,

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 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=321&type=usc&link-type=html)(q), 346a and 371.

2. In § 180.364:

a. Add alphabetically to the table in paragraph (a)(1) the following commodities.

b. Remove from the table in paragraph (a)(1), the commodities berry group 13; borage, seed; cotton, undelinted seed; crambe, seed; cranberry; flax, meal; flax, seed; fruit, citrus, group 10; fruit, pome, group 11; grape; jojoba seed; juneberry; kiwifruit; lesquerella, seed; lingonberry; meadowfoam, seed; mustard seed; rapeseed, seed; safflower, seed; salal; sesame, seed; strawberry; sunflower, seed; vegetable, bulb, group 3; vegetable, fruiting, group 8; vegetable, root and tuber, group 1, except sugar beet.

The additions read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) General. (1) * * *

Commodity	Parts per million
* * * * *	
Berry and small fruit, group 13-07	0.20
* * * * *	
Carrot	5.0
* * * * *	
Fruit, citrus, group 10-10	0.50
Fruit, pome, group 11-10	0.20
* * * * *	
Oilseeds, group 20, except canola	40
* * * * *	
Sweet potato	3.0
* * * * *	
Teff, forage	100
* * * * *	

Commodity	Parts per million
Teff, hay	100
* * * * *	
Vegetable, bulb, group 3-07	0.20
* * * * *	
Vegetable, fruiting, group 8-10 (except okra)	0.10
* * * * *	
Vegetables, root and tuber, group 1, except carrot, sweet potato, and sugar beet	0.20
* * * * *	

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