§ 180.275 Chlorothalonil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* *
Brassica, head and stem, subgroup 5A	5.0
* * *	* *
Ginseng	4.0
Horseradish	4.0
Lentil	0.10
* * *	* *
Okra	6.0
* * *	* *
Rhubarb	4.0
* * *	* *
Vegetable, cucurbit, group 9	5.0
Vegetable, fruiting, group 8, except tomato	6.0
Yam, true	0.10

* * * * *

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

(c) * * *

Commodity	Parts per million
* * *	* *
Persimmon	1.5

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0147; FRL–8385–7]

Glyphosate; Pesticide Tolerances

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 (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*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at http:/ /*www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South 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*.

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*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–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 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, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit 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*. 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.

II. Petition for Tolerance

In the **Federal Register** of May 9, 2007 (72 FR 26372) (FRL–8121– 5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 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 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*. 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)(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.

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* 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) (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) (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.

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*.

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.

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(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) 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* and is identified as docket identification number APHIS–2007–019.

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; 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.

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

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: 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(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

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 404

[Docket No. 080227317–81455–02]

RIN 0648–AW44

Papahanaumokuakea Marine National Monument Proclamation Provisions

AGENCIES: National Oceanic and Atmospheric Administration (NOAA),