

# **Exhibit 8**

**§ 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](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>, 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 online 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.

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 expression in 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<sub>50</sub> 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<sub>50</sub> 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-