

holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the docket control number [PP 4F4344/R2207], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at:

opp-docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is a paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligation of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review. Pursuant to the requirements of the Regulatory Flexibility Act (Pub L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

#### List of Subjects in 40 CFR Part 180

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

Dated: February 20, 1996.

Stephen L. Johnson,  
Director, Registration Division, Office of  
Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

#### PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.412(a), by revising the entries for corn, field, grain; corn fodder; and corn forage to read as follows.

**§ 180.412 2-[1-Ethoxyimino]butyl]-5-(2-ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * *	
corn, field, grain ....	0.5
corn fodder .....	2.5
corn forage .....	2.0
* * *	
* * *	

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BILLING CODE 6560-50-F

#### 40 CFR Part 180

[PP 5F4493/R2205; FRL-5351-5]

RIN 2070-AB78

#### Pesticide Tolerance for Glyphosate

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This rule establishes a tolerance for residues of the herbicide glyphosate [N-(phosphonomethyl)glycine] in or on the raw agricultural commodity (RAC) cotton gin byproducts at 100 parts per million (ppm). Monsanto Company requested this tolerance in a petition submitted to EPA pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA).

**EFFECTIVE DATE:** These regulations become effective February 29, 1996.

**ADDRESSES:** Written objection and hearing requests, identified by the docket number, [PP 5F4493/R2205], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing request filed with the Hearing Clerk should be identified by the docket number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 5F4493/R2205]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online

at many Federal Depository Libraries. Additional information on electronic submission can be found below in this document.

**FOR FURTHER INFORMATION CONTACT:** By mail, Robert J. Taylor, Product Manager, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 241, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703)-305-6027; e-mail: [taylor.robert@epamail.epa.gov](mailto:taylor.robert@epamail.epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA issued a notice in the Federal Register of August 17, 1995 (60 FR 42884), which announced that Monsanto Company, 700 14th Street, NW., Suite #1100, Washington, DC 20005 had submitted a petition (5F4493) proposing to amend 40 CFR part 180 pursuant to section 408 (d) of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. 346 (a), by establishing a regulation to permit residues of the herbicide glyphosate [N-(phosphonomethyl)glycine] resulting from the application of the isopropylamine salt and/or the monoammonium salt of glyphosate in or on the raw agricultural commodity (RAC) cotton gin byproducts at 100 parts per million (ppm).

There were no comments or requests for referral to an advisory committee received in response to this notice of filing.

The data submitted in the petitions and other relevant material have been evaluated. The glyphosate toxicological data listed below were considered in support of these tolerances.

1. Several acute toxicology studies placing technical-grade glyphosate in Toxicity Category III and Toxicity Category IV.

2. A 1-year feeding study with dogs fed dosage levels of 0, 20, 100, and 500 milligrams/kilogram/day (mg/kg/day) with a no-observable-effect level (NOEL) of 500 mg/kg/day.

3. A 2-year carcinogenicity study in mice fed dosage levels of 0, 150, 750, and 4,500 mg/kg/day with no carcinogenic effect at the highest dose tested (HDT) of 4,500 mg/kg/day.

4. A chronic feeding/carcinogenicity study in male and female rats fed dosage levels of 0, 3, 10, and 31 mg/kg/day (males) and 0, 3, 11, or 34 mg/kg/day (females) with no carcinogenic effects observed under the conditions of the study at dose levels up to and including 31 mg/kg/day (HDT) (males) and 34 mg/kg/day (HDT) (females) and a systemic NOEL of 31 mg/kg/day (HDT) (males) and 34 mg/kg/day (HDT) (females).

Because a maximum tolerated dose (MTD) was not reached, this study was classified as supplemental for carcinogenicity.

5. A chronic feeding/carcinogenicity study in male and female rats fed dosage levels of 0, 89, 362, and 940 mg/kg/day (males) and 0, 113, 457, and 1,183 mg/kg/day (females) with no carcinogenic effects noted under the conditions of the study at dose levels up to and including 940/1,183 mg/kg/day (males/females) (HDT) and a systemic NOEL of 362 mg/kg/day (males) based on an increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased liver weight and increased liver weight/brain ratio (relative liver weight) at 940 mg/kg/day (males) (HDT) and 457 mg/kg/day (females) based on decreased body weight gain 1,183 mg/kg/day (females) (HDT).

6. A developmental toxicity study in rats given doses of 0, 300, 1,000, and 3,500 mg/kg/day with a developmental NOEL of 1,000 mg/kg/day based on an increase in number of litters and fetuses with unossified sternebrae, and decrease in fetal body weight at 3,500 mg/kg/day, and a maternal NOEL of 1,000 mg/kg/day based on decrease in body weight gain, diarrhea, soft stools, breathing rattles, inactivity, red matter in the region of nose, mouth, forelimbs, or dorsal head, and deaths at 3,500 mg/kg/day (HDT).

7. A developmental toxicity study in rabbits given doses of 0, 75, 175, and 350 mg/kg/day with a developmental NOEL of 350 mg/kg/day (HDT); a maternal NOEL of 175 mg/kg/day based on increased incidence of soft stool, diarrhea, nasal discharge, and deaths at 350 mg/kg/day (HDT).

8. A multigeneration reproduction study with rats fed dosage levels of 0, 3, 10, and 30 mg/kg/day with a developmental NOEL of 10 mg/kg/day based on increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) of male F3b pups.

9. A two generation reproduction study with rats fed dosage levels of 0, 100, 500, and 1,500 mg/kg/day with a developmental NOEL of 500 mg/kg/day based on decreased pup body weight and body weight gain on lactation days 14 and 21 at 1,500 mg/kg/day (HDT), a systemic NOEL of 500 mg/kg/day based on soft stools in F0 and F1 males and females at 1,500 mg/kg/day (HDT) and a reproductive NOEL of 1,500 mg/kg/day (HDT).

10. Mutagenicity data included chromosomal aberration *in vitro* (no aberrations in Chinese hamster ovary cells were caused with and without S9 activation); DNA repair in rat

hepatocyte; *in vivo* bone marrow cytogenic test in rats; rec-assay with *B. subtilis*; reverse mutation test with *S. typhimurium*; Ames test with *S. typhimurium*; and dominant-lethal mutagenicity test in mice (all negative).

The reference dose (RfD) based on a developmental study with rabbits (NOEL of 175 mg/kg/bwt/day) and using a hundred-fold safety factor is calculated to be 2.0 mg/kg/bwt/day. The theoretical maximum residue contribution (TMRC) for published tolerances and food and feed additive regulations is 0.02059 mg/kg/bwt/day or 1.0 percent of the RfD for the overall U.S. population. The current action on cotton gin byproducts will not increase the TMRC or percent of the RfD. Established tolerances utilize a total of 1.0 percent of the RfD for the overall U.S. population.

For U.S. subgroup populations, nonnursing infants and children 1 to 6 years of age, the current action and previously established tolerances and the food additive regulation utilize, respectively, a total of 2.4 and 2.3 percent of the RfD, assuming that residue levels are at the established tolerance levels and that 100 percent of the crop is treated.

There are no desirable data lacking for this pesticide. There are currently no actions pending against the continued registration of this pesticide. No detectable residues of N-nitrosoglyphosate, a contaminant of glyphosate, are expected to be present in the commodities for which tolerances are established. The carcinogenic potential of glyphosate was first considered by a panel, then called the Toxicology Branch AD Hoc Committee, in 1985. The Committee, in a consensus review dated March 4, 1985, classified glyphosate as a Group C carcinogen based on an increased incidence of renal tumors in male mice. The Committee also concluded that dose levels tested in the 26-month rat study were not adequate for assessment of glyphosate's carcinogenic potential in this species. These findings, along with additional information, including a reexamination of the kidney slides from the long-term mouse study, were referred to the FIFRA Scientific Advisory Panel (SAP). In its report dated February 24, 1986, SAP classified glyphosate as a Group D Carcinogen (inadequate animal evidence of carcinogenic potential). SAP concluded that, after adjusting for the greater survival in the high-dose mice compared to concurrent controls, that no statistically significant pairwise differences existed, although the trend was significant.

The SAP determined that the carcinogenic potential of glyphosate could not be determined from existing data and proposed that the rat and/or mouse studies be repeated in order to classify these equivocal findings. On reexamination of all information, the Agency classified glyphosate as a Group D Carcinogen and requested that the rat study be repeated and that a decision on the need for a repeat mouse study would be made upon completion of review of the rat study.

Upon receipt and review of the second rat chronic feeding/carcinogenicity study, all toxicological findings for glyphosate were referred to the Health Effects Division Carcinogenicity Peer Review Committee on June 26, 1991, for discussion and evaluation of the weight-of-evidence on glyphosate with particular emphasis on its carcinogenic potential. The Peer Review Committee classified glyphosate as a Group E (evidence of noncarcinogenicity for humans), based upon lack of convincing carcinogenicity evidence in adequate studies in two animal species. This classification is based on the following findings: (1) None of the types of tumors observed in the studies (pancreatic islet cell adenomas in male rat, thyroid c-cell adenomas and/or carcinomas in male and female rats, hepatocellular adenomas and carcinomas in male rats, and renal tubular neoplasms in male mice) were determined to be compound related; (2) glyphosate was tested up to the limit dose on the rat and up to levels higher than the limit dose in mice; and (3) there is no evidence of genotoxicity for glyphosate. Accordingly, EPA concludes that glyphosate has not been "found to induce cancer when ingested by man or animal." 21 U.S.C. 348(c)(3).

The nature of the residue in plants is adequately understood, adequate methodology (HPLC) with fluorimetric detection is available for enforcement purposes, and the methodology has been published in the Pesticide Analytical Manual (PAM), Vol. II. Any secondary residues occurring in the kidney and liver of cattle, goats, horses, hogs, and sheep and liver and kidney of poultry will be covered by existing tolerances. The pesticide is considered useful for the purpose for which the regulation is sought and is capable of achieving the intended physical or technical effect.

Based on the information cited above, the Agency has determined that the establishment of this tolerance by amending 40 CFR part 180 will protect the public health. Therefore, EPA is establishing this tolerance as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections with the Hearing Clerk, at the address given above. 40 CFR 178.20. A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections. 40 CFR 178.25. Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which the hearing is requested, the requestor's contentions on each such issue, and a summary of any evidence relied upon by the objector. 40 CFR 178.27. A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested. 40 CFR 178.32.

A record has been established for this rulemaking under docket number [PP 5F4493/R2205] (including objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4.30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Va.

Written objections and hearing requests, identified by the docket number [5F4493/R2205] may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm 3708, 401 M St. SW., Washington, DC 20460. A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at:

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Clerk must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligation of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to ORB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection,  
Administrative practice and procedure,  
Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: February 20, 1996.

Stephen L. Johnson,

*Director, Registration Division, Office of  
Pesticide Programs.*

Therefore, chapter I, part 180 of title 40 of the Code of Federal Regulations is amended as follows:

#### **PART 180—[AMENDED]**

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

Authority: 21 U.S.C. a and 371.

2. In § 180.364, by amending the table in paragraph (d) by alphabetically adding the raw agricultural commodity "cotton gin byproducts" to read as follows:

#### **§ 180.364 Glyphosate; tolerances for residues.**

\* \* \* \* \*

(d) \* \* \* \*

Commodity	Parts per million
* * * *	*
Cotton gin byproducts .....	100.0
* * * *	*

[FR Doc. 96-4395 Filed 2-28-96; 8:45 am]

BILLING CODE 6560-50-F

#### **40 CFR Part 180**

[PP 4F4405/R2206; FRL-5350-8]

RIN 2070-AB78

#### **Nicosulfuron; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This document establishes tolerances for residues of the herbicide nicosulfuron [3-pyridinecarboxamide, 2-(((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)aminosulfonyl)-N,N-dimethyl] in or on the raw agricultural commodities (RACs) corn, sweet (kernels plus cobs with husks removed) at 0.1 part per million (ppm); corn, sweet, forage at 0.1 ppm and corn, sweet, fodder (stover) at 0.1 ppm. E.I. du Pont de Nemours and Company, Inc., requested these tolerances in a petition submitted to EPA pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA).

**EFFECTIVE DATE:** This regulation becomes effective February 29, 1996.

**ADDRESSES:** Written objections and hearing requests, identified by the document control number [PP4405/R2206], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing request filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP4F4405/R2206]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

**FOR FURTHER INFORMATION CONTACT:** By mail, Robert J. Taylor, Product Manager (PM-25), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 241, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-6027; e-mail: taylor.robert@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of February 8, 1995 (60 FR 7540), EPA issued a notice announcing that Du Pont, Agricultural Products, Barley Mill, P.O. Box 80038, Wilmington, DE 19880-0038, had submitted a pesticide petition (PP4F4405) proposing to amend 40 CFR

part 180 by establishing a regulation under section 408(d) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a(d)) to permit residues of the herbicide nicosulfuron (3-pyridinecarboxamide, 2-(((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)aminosulfonyl)-N,N-dimethyl), in or on corn, sweet (kernels plus cobs with husks removed) at 0.1 part per million (ppm) and corn, sweet, forage at 0.1 ppm. There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

The petitioner subsequently amended the petition by submitting a revised Section F proposing to establish tolerances for nicosulfuron in or on the RACs corn, sweet (Kernels plus cobs with Husks Removed) at 0.1 ppm; corn, sweet, forage at 0.1 ppm, and corn, sweet, fodder (stover) at 0.1 ppm. In the Federal Register of September 13, 1995 (60 FR 47578), EPA issued an amended filing notice proposing these tolerances. The Agency received one comment opposing these tolerances. The commenter's opposition to the tolerance was based upon toxicological concerns including the concept of "NOEL" (No observed effect level); the use of animal testing to represent human reaction to potentially toxic substances (pesticides); the indications of a link between pesticide exposure and Parkinson's Disease (PD).

The Agency has reviewed the comment and decided to proceed with these tolerances. The Agency, made the decision that a wide variety of toxicological studies would serve as the basis for determining if a pesticide could be registered and used without unreasonable risk. It is true that animal models do not and cannot predict every possible human reaction to pesticides, but the general consensus is that they offer the best information as to what a pesticide might do to humans. Usually, the Agency requires and reviews long-term studies in rodents and non-rodents to determine a dose which causes no apparent adverse effects. The NOEL is divided by an uncertainty factor - often at least 100 - to arrive at doses or exposures that should not cause harmful effects on humans. In the Agency's regulation of pesticides, the Agency does not approve uses which will cause unreasonable adverse effects to humans or the environment.

The Agency understands that the testing of one pesticide at a time does not predict all the possible adverse interactions with other pesticides - or for that matter other drugs or environmental pollutants. The Agency is exploring ways of testing for the