

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
* * * *	*

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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

interactions of pesticides having similar toxicity endpoint, but progress in that area is slow.

With reference to the indications of a link between pesticide exposure and Parkinson's Disease, the Agency is aware that many researchers are investigating the potential reaction of pesticide exposures to chronic neurological diseases including Parkinson's Disease, and additional research is needed to study this important area. Available studies in humans or animals have not yet established any relationship between pesticide exposures and Parkinson's Disease.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data listed below were considered in support of this tolerance.

1. Several acute toxicology studies placing the technical-grade herbicide in Toxicity Category III.

2. A 1-year feeding study with dogs fed dosages of 0, 6.25, 125, and 500 mg/kg/day resulted in a systemic NOEL of 125 mg/kg/day in males based upon a decrease in body weight gains and a concomitant increase in relative liver and kidney weights in males. The NOEL for females was 500 mg/kg/day, the highest dose tested (HDT).

3. A 2-year chronic toxicity/carcinogenicity study with rats fed dosages of 0, 1.9/2.6, 58.1/77.1, 289/382, and 786/1,098 mg/kg/day (males/females) demonstrated that no carcinogenic effects were observed under the conditions of the study at dose levels up to and including 786/1,098 (males/females) mg/kg/day (HDT) and a systemic NOEL equal to or greater than 786 mg/kg/day (males) and 1,098 mg/kg/day (females), (HDT).

4. An 18-month carcinogenicity study with mice fed dosages of 0, 3.3/4.4, 32.7/44.8, 327/438, and 993/1,312 mg/kg/day (males/females) demonstrated that no carcinogenic effects were observed under the conditions of the study up to and including 993/1,312 (males/females) mg/kg/day (HDT) and a systemic NOEL of 993/1,312 (males/females) mg/kg/day (HDT).

5. A developmental toxicity study in rats fed dosages of 0, 200, 1,000, 2,500, and 6,000 mg/kg/day had a developmental and maternal NOEL equal to or greater than 6,000 mg/kg/day, (HDT).

6. A developmental toxicity study in rabbits fed dosages of 0, 100, 500, 1,000, and 2,000 mg/kg/day had a maternal NOEL of 100 mg/kg/day based upon maternal toxicity occurring at 500 mg/kg/day. Maternal toxicity was demonstrated by an increase in clinical

signs, gross pathological observations, abortions, postimplantation loss and decrease in body weight gain during the dosing period. The developmental NOEL was 500 mg/kg/day based upon developmental toxicity evidenced at 1,000 mg/kg/day in the form of reduced mean fetal body weights and the apparent increase in postimplantation loss at 500 mg/kg/day and above.

7. A multi-generation reproduction study in the rat administered dosages of 0, 12.5, 287, and 1,269 mg/kg/day had a systemic NOEL of 287 mg/kg/day based upon F1 (first mating) females with a lower body weight gain during the final week of gestation and a similar pattern in the F0 females during the same period of gestation at 1,269 mg/kg/day (HDT). The reproductive NOEL was 287 mg/kg/day based on a minimal reduction of litter size at birth and in pup weights at postpartum days 14 through 21 in the F2a high-dose group at 1,269 mg/kg/day (HDT).

8. A mutagenic test with *Salmonella typhimurium* did not show mutagenicity in four test strains (TA97A, TA98, TA100, and TA1535) with or without metabolic activation; *in vitro* chromosomal aberration test in cultured human lymphocytes indicated negative response at the concentrations of 40 to 470 ug/mL; an unscheduled DNA damage assay at the concentrations of 0.04 to 470 ug/mL was negative; *in vitro* gene mutation assay in Chinese hamster ovary cells was nonmutagenic at the concentrations of 4 to 465 ug/mL with or without metabolic activation; and a micronucleus assay in mouse bone marrow had negative responses at the dose levels of 500 to 5,000 mg/kg.

The reference dose (RFD), based on a 1 year dog feeding study (NOEL of 125 mg/kg bwt/day) and using a hundred fold safety factor, is calculated to be 1.25 mg/kg bwt/day. The theoretical maximum residue contribution (TMRC) for the existing tolerances is 0.000034 mg/kg/day and utilizes 0.003% of the RFD. The current action will increase the TMRC by 0.000024 mg/kg/day. These tolerances and previously established tolerances will utilize a total of 0.005% of the RFD for the overall U.S. population. For U.S. subgroup populations nonnursing infants and children 1 to 6, the current action and previously established tolerances utilize 0.011% of the RFD, assuming that residue levels are at the established tolerances and 100% of the crop is treated.

No desirable data are lacking. The pesticide is useful for the purpose for which the tolerance is sought. Adequate analytical methodology (liquid chromatography with ultraviolet

detection) is available for enforcement purposes. The method is not yet published in the Pesticide Analytical Manual (PAM), but can be obtained as follows: by mail: Calvin Furlow, Public Information Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location and telephone number: Crystal Mall #2, Rm 1130A, 1921 Jefferson Davis Hwy., Arlington, VA, (703-305-5937).

There are currently no actions pending against the registration of this chemical. No secondary residues are expected to occur in poultry, meat, meat byproducts, or eggs based on the proposed use on sweet corn, since sweet corn is not fed to poultry. No secondary residues are expected to occur in milk and the meat, and meat byproducts of cattle, goats, hogs, horses and sheep.

Based on the information cited above, the Agency has determined that the establishment of the tolerances by amending 40 CFR part 180 will protect the public health; therefore, the tolerances are established 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 in 40 CFR 180.33 (i). If a hearing is requested, the objections must include a statement of factual issue(s) on which a 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 of such 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 4F4405/R2206] (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 control number [PP 4F4405/R2206] 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 the 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, 21 U.S.C. 601-612), the Administrator has determined that regulations establishing new 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, 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 section 180.454 by amending the table therein by adding and alphabetically inserting new entries for corn, sweet (kernels plus cobs with husks removed); corn, sweet, fodder (stover); and corn, sweet, forage; to read as follows:

§ 180.454 Nicosulfuron, [3-pyridinecarboxamide, 2-(((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)aminosulfonyl)-N,N-dimethyl]; tolerances for residues.

Commodity	Parts per million
* * * * *	
corn, sweet (kernels plus cobs with husks removed)	0.1

Commodity	Parts per million
corn sweet, fodder (stover)	0.1
corn, sweet, forage	0.1

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40 CFR Parts 180 and 186

[PP 3F4169 and FAP 3H5655/R2200; FRL-4996-2]

RIN 2070-AC78

Imidacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is establishing permanent tolerances for residues of the insecticide (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine) (also known as imidacloprid) and its metabolites in or on cottonseed and cotton gin byproducts, revoking the existing feed additive tolerance for imidacloprid on cotton meal, and establishing a maximum residue limit for imidacloprid on cottonseed meal. Bayer Corporation (formerly Miles, Inc.) submitted petitions pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) requesting these regulations to establish certain maximum permissible levels for residues of the insecticide.

EFFECTIVE DATE: This regulation is effective on February 15, 1996.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 3F4169 and FAP 3H5655/R2200], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests 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 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M,