

the order defies 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 obligations 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, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 9, 1995.

**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 § 180.417 by amending paragraph (b) by revising the table therein, to read as follows:

**§ 180.417 Triclopyr; tolerances for residues.**

*	*	*	*	*
(b) * * *				

Commodity	Parts per million
Eggs .....	0.05
Meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep .....	0.05
Meat, fat, and meat byproducts (except kidney) of poultry .....	0.1
Milk .....	0.01
Liver and kidney of cattle, goats, hogs, horses, and sheep .....	0.5
Rice, grain .....	0.3
Rice, straw .....	10.0

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**40 CFR Part 180**

[PP 1F3986, PP 1F3987, and PP 1F3988/R2098; FRL-4928-6]

RIN 2070-AB78

**Sodium 5-Nitroguaiacolate, Sodium O-Nitrophenolate, and Sodium P-Nitrophenolate; Exemptions from the Requirement of a Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This rule establishes exemptions from the requirement of a tolerance for residues of the biochemical plant regulators sodium 5-nitroguaiacolate, sodium o-nitrophenolate, and sodium p-nitrophenolate in or on the raw agricultural commodities cottonseed, cotton gin byproducts, rice, rice straw, soybeans, and soybean forage and hay when products containing 0.1%, 0.2%, and 0.3% by weight of these active ingredients, respectively, are applied at rates of 20 grams of each active ingredient per acre or less per application in accordance with good agricultural practices. These exemptions were requested by Asahi Chemical Manufacturing Co., Ltd.

**EFFECTIVE DATE:** Effective on January 9, 1995.

**ADDRESSES:** Written objections and hearing requests, identified by the document control number, [PP 1F3986, PP 1F3987, and PP 1F3988/R2098], 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 a copy of the 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, Pittsburgh, PA 15251.

**FOR FURTHER INFORMATION CONTACT:** By mail: Leonard S. Cole, Jr., Acting Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 305-6900.

**SUPPLEMENTARY INFORMATION:** EPA issued a notice, published in the **Federal Register** of December 13, 1991 (56 FR 65080), which announced that Asahi Chemical Manufacturing Co., Ltd., 500 Takayasu, IkarugaCho, Ikoma-Gun, Nara Prefecture, Japan, had submitted pesticide petitions (PP) 1F3986, 1F3987, and 1F3988 proposing to amend 40 CFR part 180 by establishing a regulation pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a and 371, to exempt from the requirement of a tolerance the residues of the biochemical plant regulators sodium 5-nitroguaiacolate, sodium o-nitrophenolate, and sodium p-nitrophenolate when applied at rates of 20 grams of active ingredient or less per acre per application in or on the raw agricultural commodities from application to cotton, rice, and soybeans.

No comments were received in response to the **Federal Register** notice.

The data submitted in the petitions and all other relevant material have been evaluated. The toxicological data considered in support of the exemptions from the requirement of a tolerance include acute toxicity tests, subchronic oral toxicity tests, developmental toxicity studies, and mutagenicity studies. Acute toxicity tests place the end-use product in Toxicity Category IV. The acute toxicity tests for the individual technical chemicals indicate that sodium 5-nitroguaiacolate is in Toxicity Category I based on primary eye irritation, sodium p-nitrophenolate is in Toxicity Category II based on acute oral toxicity and primary eye irritation, and sodium o-nitrophenolate is in Toxicity Category II based on primary

eye irritation. Atonik is a mild dermal sensitizer.

Atonik, the end-use product, containing 0.3% sodium *p*-nitrophenolate, 0.2% sodium *o*-nitrophenolate, and 0.1% sodium 5-nitroguaiacolate by weight, was fed to rats in the subchronic oral toxicity test at dietary levels of 0, 5,000, 15,000 and 50,000 parts per million (ppm), which was equivalent to 515, 1,589, and 5,056 mg/kg/day for males and 531, 1,723, and 6,553 mg/kg/day for females. Based on decreased weight gains, changes in hematology parameters, relative organ weights of liver and kidney, and pigment accumulation in kidney and spleen, the lowest-observed-effect level (LOEL) is approximately 1,600 mg/kg/day (1,589 and 1,723 mg/kg/day in males and females, respectively). The no-observed-effect level (NOEL) is approximately 525 mg/kg/day (515 and 531 mg/kg/day in males and females, respectively).

In a developmental toxicity study, Atonik was administered to rats by gastric gavage at dose levels of 0, 100, 300, and 600 mg/kg/day. Maternal toxicity was observed at the 600 mg/kg/day level, manifested as significantly decreased body weight gain and food consumption. One death at this dose level was considered to be treatment related. Based on these results, the maternal toxicity NOEL and LOEL were 300 and 600 mg/kg/day, respectively. Developmental toxicity was not observed in this study. The NOEL for developmental toxicity was 600 mg/kg/day, and the LOEL was not determined.

In mutagenicity studies, the individual active ingredients were negative for mutagenicity when tested using the Ames Test, the Mouse Micronucleus Assay, and the Mouse Lymphoma Assay.

All of the toxicity studies submitted are considered acceptable. The toxicity data provided are sufficient to show that there are no foreseeable human or domestic animal health hazards likely to arise from the use of these active ingredients as plant regulators in the concentrations present in the end-use product and applied at rates of 20 grams of each active ingredient or less per acre.

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to these petitions. Chronic exposure data upon which ADI and MPI values are based are not required for pesticides which are classified as biochemicals and applied at rates of 20 grams or less of each active ingredient per acre. Although the individual active ingredients are acutely toxic in certain tests, the end-use

product containing the combined active ingredients at the concentrations specified above was in the lowest toxicity category. At application rates of 20 grams per acre or less, the level of active ingredient which may be present in any of the food or feed items would be far below levels which demonstrated any effects in the subchronic oral toxicity test, developmental toxicity studies, and mutagenicity studies. For example, in order to reach a dosage rate comparable to the LOEL (1,600 mg/kg/day) obtained in the subchronic oral toxicity study, it is calculated that a person weighing 50 kg would need to consume all of the produce from 4 acres of crop every day.

Because the tolerance exemption does not define a permitted residue level in food, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request. This is the first exemption from the requirement of a tolerance for the active ingredients, sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate, and sodium *p*-nitrophenolate. By way of public reminder, this notice also reiterates the registrant's responsibility under section 6(a)(2) of FIFRA, to submit additional factual information regarding adverse effects on the environment and to human health by these pesticides.

These active ingredients are considered useful for the purpose for which the exemptions from the requirement of a tolerance are sought. Based on the information considered, the Agency concludes that establishment of the exemptions will protect the public health. Therefore, the regulation is 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. 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 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 to the contrary; and resolution of factual issue(s) in the manner sought by the requestor would

be adequate to justify the action requested. 40 CFR 178.32.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to 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 known 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 (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 this 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 an 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 procedures, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 9, 1995.

**Stephen L. Johnson**,  
*Acting Director, Office of Pesticide Programs.*

Therefore, 40 CFR part 180 is amended as follows:

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

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

2. In subpart D, by adding new §§ 180.1139, 180.1140, and 180.1141, to read as follows:

**§ 180.1139 Sodium 5-nitroguaiacolate; exemption from the requirement of a tolerance.**

The biochemical sodium 5-nitroguaiacolate is exempted from the requirement of a tolerance when used as a plant regulator in end-use products at a concentration of 0.1% by weight and applied at an application rate of 20 grams of active ingredient per acre (20 g ai/A) or less per application, in or on the raw agricultural commodities cottonseed, cotton gin byproducts, rice, rice straw, soybeans, and soybean forage and hay.

**§ 180.1140 Sodium o-nitrophenolate; exemption from the requirement of a tolerance.**

The biochemical sodium o-nitrophenolate is exempted from the requirement of a tolerance when used as a plant regulator in end-use products at a concentration of 0.2% by weight and applied at an application rate of 20 grams of active ingredient per acre (20 g ai/A) or less per application, in or on the raw agricultural commodities cottonseed, cotton gin byproducts, rice, rice straw, soybeans, and soybean forage and hay.

**§ 180.1141 Sodium p-nitrophenolate; exemption from the requirement of a tolerance.**

The biochemical sodium p-nitrophenolate is exempted from the requirement of a tolerance when used as a plant regulator in end-use products at a concentration of 0.3% by weight and applied at an application rate of 20 grams of active ingredient per acre (20 g ai/A) or less per application, in or on the raw agricultural commodities cottonseed, cotton gin by-products, rice, rice straw, soybeans and soybean forage and hay.

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**40 CFR Parts 180 and 186**

[PP 2F4041, FAP 2H5621/R2103; FRL-4931-2]

RIN 2070-AB78

**Pesticide Tolerance and Feed Additive Regulation for Sethoxydim**

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

**ACTION:** Final rule.

**SUMMARY:** This document establishes a pesticide tolerance for the combined residues of the herbicide sethoxydim, 2-[1-ethoxyimino) butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one), and its metabolites

containing the 2-cyclohexene-1-one moiety (calculated as the herbicide) in or on the raw agricultural commodity (RAC) canola/rapeseed at 35.0 parts per million (ppm) and a feed additive regulation in or on animal feed commodity canola/rapeseed meal at 40 ppm. BASF Corp. requested these regulations to establish maximum permissible levels for residues of the pesticide in or on the commodities.

**EFFECTIVE DATE:** This regulation becomes effective January 20, 1995.

**ADDRESSES:** Written objections and hearing requests, identified by the document control number, [PP 2F4041, FAP 2H5261/R2103], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of 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 request 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 36277M, Pittsburgh, PA 15251.

**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 and telephone number: Rm. 245, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 305-6800.

**SUPPLEMENTARY INFORMATION:** EPA issued a notice, published in the **Federal Register** of March 11, 1992 (57 FR 8658), which announced that BASF Corp., P.O. Box 13528, Research Triangle Park, NC 27709-3528, had submitted pesticide petition (PP) 2F4041. EPA issued a notice, published in the **Federal Register** of June 10, 1992 (57 FR 24646) that the company had submitted feed additive petition (FAP) 2H5621. PP 2F4041 requests that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), amend 40 CFR part 180 by establishing a tolerance for the combined residues of the herbicide sethoxydim, 2-[1-ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-

cyclohexene-1-one) and its metabolites containing the 2-cyclohexene-1-one moiety (calculated as the herbicide) in or on the raw agricultural commodity (RAC) canola/rapeseed at 35.0 parts per million. FAP 2H5621 requests that the Administrator, pursuant to section 409(e) of the FFDCA (21 U.S.C. 348(e)), amend 40 CFR part 186 by establishing a feed additive regulation for combined residues of the herbicide sethoxydim, 2-[1-ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one), and its metabolites containing the 2-cyclohexene-1-one moiety (calculated as the herbicide) in or on animal feed commodity canola/rapeseed meal at 40 ppm.

No comments were received in response to these notices of filing.

The scientific data submitted in the petitions and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances include:

1. Several acute toxicology studies placing technical sethoxydim in acute toxicity category IV for primary eye and dermal irritation and acute toxicity category III for acute oral, dermal, and inhalation. The dermal sensitization-guinea pig study was waived because no sensitization was seen in guinea pigs dosed with the end-use product Poast (18% a.i.).

2. A 21-day dermal study with rabbits fed dosages of 0, 40, 200, and 1,000 mg/kg/day with a NOAEL (no-observed-adverse-effect level) of greater than 1,000 mg/kg/day (limit dose).

3. A 1-year feeding study with dogs fed dosages (based on consumption) of 0, 8.86/9.41, 17.5/19.9, and 110/129 mg/kg/day (males/females) with a NOEL of 8.86/9.41 mg/kg/day (males/females) based on equivocal anemia in males and females at 17.5/19.9 mg/kg/day, respectively.

4. A 2-year chronic feeding/carcinogenicity study with mice fed dosages of 0, 6, 18, 54, and 162 mg/kg/day with no carcinogenic effects observed under the conditions of the study at dose levels up to and including 162 mg/kg/day (highest dose tested [HDT]) and a systemic NOEL of 18 mg/kg/day.

5. A 2-year chronic feeding/carcinogenic study with rats fed dosages of 0, 2, 6, and 18 mg/kg/day (HDT) with no carcinogenic effects observed under the conditions of the study at dosage levels up to and including 18 mg/kg/day (HDT) and a systemic NOEL greater than or equal to 18 mg/kg/day (HDT). This study was reviewed under current guidelines and was found to be unacceptable because the doses used