

this section, the "medical benefits package" does not include the following:

- (1) Abortions and abortion counseling.
- (2) Drugs, biologicals, and medical devices not approved by the Food and Drug Administration unless the treating medical facility is conducting formal clinical trials under an Investigational Device Exemption (IDE) or an Investigational New Drug (IND) application, or the drugs, biologicals, or medical devices are prescribed under a compassionate use exemption.
- (3) Gender alterations.
- (4) Hospital and outpatient care for a veteran who is either a patient or inmate in an institution of another government agency if that agency has a duty to give the care or services.
- (5) Infertility services.
- (6) Membership in spas and health clubs.
- (7) Pregnancy and delivery.
- (8) Reproductive sterilization, unless medically necessary.
- (9) Surgery to reverse voluntary sterilization.
- (10) Surgical implantation of penile prostheses.

(Authority: 38 U.S.C. 101, 501, 1701, 1705, 1710, 1721, 1722)

#### § 17.43 [Amended]

5-6. In § 17.43, paragraph (a) is removed and paragraphs (b) through (e) are redesignated as paragraphs (a) through (d), respectively.

#### § 17.47 [Amended]

7. In § 17.47, paragraph (h) is removed; paragraphs (i) through (l) are redesignated as paragraphs (h) through (k), respectively; and newly redesignated paragraph (h) is amended by removing "hospital or" and by removing "or hospital care in a Federal hospital under agreement,".

#### § 17.93 [Amended]

8. In § 17.93, paragraph (a)(2) is amended by removing "Medical services" and adding, in its place, "Subject to the provisions of §§ 17.36 through 17.38, medical services".

#### § 17.99 [Removed]

9. Section 17.99 is removed.

#### § 17.100 [Amended]

10. In § 17.100, the third sentence is amended by removing "a new application is filed, and".

[FR Doc. 98-18302 Filed 7-9-98; 8:45 am]

BILLING CODE 8320-01-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[OH 114-1b; FRL-6123-2]

#### Approval and Promulgation of Maintenance Plan Revision; Ohio

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule.

**SUMMARY:** The United States Environmental Protection Agency (EPA) is proposing to approve a March 13, 1998, request from Ohio, for a State Implementation Plan maintenance plan revision for the Columbus ozone maintenance area. The maintenance plan revision establishes an out year of 2010 for the area's emissions budget. The maintenance plan revision also allocates to the 2010 mobile source emissions budget a portion of the area's safety margin. The 2010 mobile source emissions budget will be used for transportation conformity purposes. The safety margin is the difference between the attainment inventory level of the total emissions and the projected levels of the total emissions in the final year of the maintenance plan.

In the final rules section of this **Federal Register**, EPA is approving the State's requests as a direct final rule without prior proposal because EPA views this action as noncontroversial and anticipates no adverse comments. A detailed rationale for approving the State's request is set forth in the direct final rule. The direct final rule will become effective without further notice unless the Agency receives relevant adverse written comment on the rule. Should the Agency receive such comment, it will publish a notice informing the public that the direct final rule did not take effect and such public comment received will be addressed in a subsequent final rule based on this proposed rule. If no adverse written comments are received, the direct final rule will take effect on the date stated in that document and no further activity will be taken on this proposed rule. EPA does not plan to institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

**DATES:** Written comments on this proposed action must be received by August 10, 1998.

**ADDRESSES:** Written comments should be sent to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch, (AR-18J), U.S. Environmental Protection Agency,

Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

#### FOR FURTHER INFORMATION CONTACT:

Scott Hamilton, Environmental Scientist, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-4775.

**SUPPLEMENTARY INFORMATION:** For additional information, see the Direct Final document which is located in the Rules section of this **Federal Register**. Copies of the requests are available for inspection at the following address: (Please contact Scott Hamilton at (312) 353-4775 before visiting the Region 5 office.) USEPA Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604-3590.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Ozone, Nitrogen oxides, Transportation conformity.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: July 1, 1998.

**David A. Ullrich,**

*Acting Regional Administrator.*

[FR Doc. 98-18421 Filed 7-9-98; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-300680; FRL-6016-1]

### 40 CFR Part 180

RIN 2070-AB18

#### Food and Food By-Products Used as a Pesticide; Proposed Exemption From the Requirement of a Tolerance

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to establish an exemption from the requirement of a tolerance for residues of any edible food commodity (except for peanuts, tree nuts, milk, soybean, eggs, fish, crustacea, and wheat) used as a pesticide, when applied in accordance with good agricultural practices, in or on all food commodities. Any edible food commodity used as a pesticide under this exemption must not be "adulterated food" as defined in FFDCA section 402.21 U.S.C. 342. The exemption from the requirement of a tolerance is being proposed by the Agency on its own initiative, since the

Agency believes that the exemption for edible food commodities will be safe.

**DATES:** Comments, identified by the docket control number [OPP-300680], must be received on or before September 8, 1998.

**ADDRESSES:** By mail, submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by following the instructions under Unit IV of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

**FOR FURTHER INFORMATION CONTACT:** By mail: Freshteh Toghrol, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Station #1, 5th Floor, 2805 Crystal Drive, Arlington, VA 22202; (703) 308-7014; toghrol.freshsteh@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 408(e) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), EPA proposes to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of any edible food commodity (except for peanuts, tree nuts, milk, eggs, fish, crustacea, and wheat) used as a pesticide, when applied in accordance with good agricultural practices in or on all food commodities. By edible food commodity, EPA means foods that are widely consumed for their nutrient properties. This exemption would not apply to any "adulterated food" under FFDCA section 402.

### I. Statutory Authority

New section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption from tolerance is "safe." Section 408(c)(2)(A)(ii) 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(c)(2)(B) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption 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...." EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### II. Risk Assessment and Statutory Findings

Under the conditions of the proposed tolerance exemption for residues of any edible food commodity used as a pesticide (as defined above) in or on all food commodities, and in consideration of the conditions, criteria, and requirements set forth by FQPA, the Agency believes that this tolerance exemption will be safe for humans, including infants and children. This exemption only applies to those foods that have been widely consumed for their nutrient properties. Any safety concerns regarding exposure to residues of such edible food commodities have been addressed by the long history of safe use of these foods in commerce, as well as the adequate regulation of foods by the Food and Drug Administration. Additionally, any cumulative effects from aggregate exposure to residues of food commodities when used as pesticides in or on other food commodities would not likely impact those effects that may occur from much broader exposure via consumption of food in the diet.

Some edible foods produce an allergic reaction in certain individuals. Allergy to food proteins occurs in less than 1 to

2% of the population. The majority of individuals with documented immunologic reactions to foods exhibit immunoglobulin E (IgE)-mediated immediate hypersensitivity reactions that can be sudden and severe. Current scientific knowledge suggest that common food allergens are glycosylated proteins, which tends to be resistant to degradation by heat, acid, and proteases. Where food allergy is confirmed patients are usually allergic to only a few specific proteins within one or two specific foods. Eight food or food groups (peanut, soybean, tree nuts, milk, eggs, fish, crustacea, and wheat) account for the vast majority of documented food allergies worldwide (the Food and Agriculture Organization (FAO) of the United Nation: Report of the FAO Technical Consultation on Food Allergies, Rome, Italy, November 13-14, 1995). Even though, as explained below, there are unlikely to be significant residues from use of edible food as a pesticide, the Agency has decided not to include those known allergenic food commodities in this exemption.

The Agency believes that food commodities will be used as pesticides to control or mitigate pests or as plant growth regulators in only very limited cases. It is unlikely that an edible food commodity could be used to control a pest via a toxic mode of action. This assumption is supported by the Agency's experience to date where food commodities have been used to attract, repel or otherwise suppress pests. The purported mechanisms of action for food commodities involve feeding deterrence for herbivorous insects or mammals or an alteration in the microbial flora which suppresses the microbial pests. In the case of an altered microbial populations, it is necessary for the food commodity to be degraded or metabolized before the desired effect can occur.

The Agency also believes that residues from any edible food commodity, when used as a pesticide on another food commodity would be minimal to non-existent because of rapid degradation in the environment.

No tolerances or exemptions from requirements of tolerances have been issued in the United States or internationally for all food commodities as biochemical pesticides; however, some individual foods or food by-products have tolerance exemptions in the United States.

### III. Safety Determination for U.S. Population and Infants and Children

The Agency believes that this tolerance exemption will be safe for humans, including infants and children.

Any safety concerns regarding exposure to residues of edible food commodities have been addressed by the long history of safe use of foods in commerce, as well as the adequate regulation of foods by the Food and Drug Administration. Additionally, any cumulative effects from aggregate exposure to residues of food commodities when used as pesticides in or on other food commodities would not likely impact those effects that may occur from much broader exposure via consumption of food in the diet. Since food commodities are non toxic to humans including infants and children, EPA has not assessed the risk from food commodities using a safety factor approach. Accordingly, application of an additional 10X safety factor analysis or quantitative risk assessment for the protection of infants and children is not necessary to protect the safety of infants and children.

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Based on the information and data considered, the Agency has determined that, in amending 40 CFR 180.1164, as proposed, there is reasonable certainty that no harm to the general population, including infants and children will result from aggregate exposure to edible food commodities used as pesticides. An exemption from tolerance is appropriate for these pesticides because EPA believes they do not pose a dietary risk under reasonably foreseeable circumstances. Accordingly, EPA proposes that the exemption from the requirement of a tolerance be established as set forth below.

#### IV. Public Docket and Electronic Submissions

The official record for this rule making, as well as the public version, has been established for this rule making under document control number [OPP-300680] (including comments and data submitted electronically). 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. 22202.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov

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

The official record for this rule making, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of comments received electronically into printed paper form as they are received and will place the paper copies in the official rule making record. The official rule making record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

#### V. Regulatory Assessment Requirements

This rule proposes an exemption from the requirement of a tolerance under FFDC section 408(d). The EPA is proposing this regulation on its own initiative. 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). This action does not contain any information collections subject to OMB approval under the *Paperwork Reduction Act* (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the *Unfunded Mandates Reform Act of 1995* (UMRA; Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629), February 16, 1994, or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the

Chief Counsel for Advocacy of the Small Business Administration.

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

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and record keeping requirements.

Dated: June 29, 1998.

**Kathleen D. Knox,**

*Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I, part 180 is proposed to be 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. Section 180.1164 is amended by adding paragraph (d) to read as follows:

**§ 180.1164 Food and food by-products; exemption from the requirement of a tolerance.**

\* \* \* \* \*

(d) Any edible food commodity (except for peanuts, tree nuts, milk, eggs, fish, crustacea, and wheat) used as a pesticide is exempted from the requirement of a tolerance when used in accordance with good agricultural practice in or on all food commodities. This exemption shall not apply to any edible food commodity that is adulterated under section 342 of Title 21 of the United States Code.

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Parts 264 and 265

[IL-64-2-5807; FRL-6122-8]

#### Project XL Site-specific Rulemaking for OSi Specialties, Inc., Sistersville, WV

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

**ACTION:** Supplemental proposal.

**SUMMARY:** This document proposes a narrow modification being considered by the EPA in implementing a project under the Project XL program for the OSi Specialties, Inc., plant, a wholly owned subsidiary of Witco Corporation, located near Sistersville, West Virginia ("the Sistersville Plant"). To implement this XL project, the EPA proposed on March 6, 1998, a site-specific regulatory deferral of certain air emission standards. That action has not yet been