

List of Subjects in 40 CFR Part 131

Environmental protection, Water pollution, Water quality standards.

Robert Perciasepe,

Assistant Administrator for Water.

[FR Doc. 97-18970 Filed 7-17-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300505; FRL-5717-8]

Corn Gluten; Proposed Exemption From the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: EPA is proposing to establish an exemption from the requirement of a tolerance for residues of the biochemical pesticide corn gluten, also known as corn gluten meal, when used as a herbicide in or on various food commodities. The exemption from the requirement of a tolerance is being proposed by the Agency on its own initiative.

DATES: Comments, identified by the docket control number [OPP-300505], must be received on or before September 16, 1997.

ADDRESSES: By mail, submit written comments to: Information and Records Integrity Branch, Public Information and Services Division (7506C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

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). CBI should not be submitted through e-mail. Information marked as CBI 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 may be disclosed publicly by EPA without prior notice. All written comments will be available for public

inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Freshteh Toghrol, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th Floor, Crystal Station 1, 2805 Crystal Drive, Arlington, VA; Telephone number (703) 308-7014, e-mail:

toghrol.freshteh@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA) and 21 U.S.C. 346a(d), EPA proposes to amend 40 CFR 180.1164 by establishing an exemption from the requirement of a tolerance for residues of the biochemical pesticide corn gluten, also known as corn gluten meal, when applied in accordance with good agricultural practices in or on all food commodities. Pursuant to section 408(d)(2)(a)(i) of the FFDCA, as amended, the Agency is issuing this proposed exemption on its own initiative.

I. Corn Gluten

Corn gluten is classified by Food and Drug Administration as GRAS (Direct Food Substances Affirmed As Generally Recognized As Safe, 21 CFR 184.1321).

A. Proposed Use Practices

Corn gluten, also known as corn gluten meal, is proposed to be used as an herbicide in or on all food commodities. The rate of application and number of applications will not be limited because corn gluten is a protein (food-by product) obtained from corn.

B. Product Identity/Chemistry

1. *Corn gluten.* Corn gluten (Cas Reg. No. 66071-96-3), also known as corn gluten meal, is the principal protein component of corn endosperm. It consists mainly of zein and glutelin, and is a by-product of the wet milling of corn for starch. The gluten fraction is washed to remove residual water soluble proteins. Corn gluten is also produced as a by-product during the conversion of the starch in whole or various fractions of dry milled corn to corn syrups.

a. The ingredient is used as a nutrient supplement as defined in 21 CFR 170.3(o)(20) and a texturizer as defined in 21 CFR 170.3(o)(32).

b. The ingredient is used in food at levels not to exceed current good manufacturing practice.

c. Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Corn gluten is also classified by EPA as a pesticide not requiring Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulation (Exemptions For Pesticides of a Character Not Requiring FIFRA Regulation, 40 CFR 152.25). Corn gluten is listed under 40 CFR 152.25(g)(1):

§ 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.

* * * * *

(g) *Minimum risk pesticides*—(1) *Exempted products.* Products containing the following active ingredients are exempt from the requirements of FIFRA, alone or in combination with other substances listed in this paragraph, provided that all of the criteria of this section are met.

* * * * *

(2) *Permitted inerts.* A pesticide product exempt under paragraph (g)(1) of this section may only include inert ingredients listed in the most current List 4A * * *

(3) *Other conditions of exemption.* All of the following conditions must be met for products to be exempted under this section:

(i) Each product containing the substance must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient.

(ii) The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease transmitting bacteria or viruses, or claim to control insects or rodents carrying specific diseases, including, but not limited to ticks that carry Lyme disease.

(iii) The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10 (a)(5)(i) through (viii).

Based upon the information provided above, EPA has found that when corn gluten is used in accordance with good agricultural practice, the ingredient is useful and a tolerance is not necessary to protect public health. Therefore, EPA proposes that an exemption from the requirement of a tolerance be established for residues of the herbicide corn gluten, when used as an active ingredient for end-use formulations.

2. *Magnitude of Residue.* The Agency believes that corn gluten residues are non-toxic since corn gluten occurs naturally in food and the environment.

3. *Analytical method.* The analytical method is not needed because corn gluten residues consist of proteins, which will not be distinguishable from those proteins present in the crop.

C. Mammalian Toxicological Profile

Corn gluten is a protein found in food consumed by humans, and animals, and

is non-toxic to humans, and animals. The Agency therefore, supports the exemption from the requirement of a tolerance for corn gluten.

D. Aggregate Exposure

1. *Dietary exposure.* Under this proposed tolerance exemption, oral exposure to crops containing corn gluten may occur; however, due to the product's lack of mammalian toxicity, such exposure will not be harmful to humans.

2. *Drinking water and non dietary exposure.* Corn gluten is a food by-product and its use in residential, home garden, or lawn care situations, as well as other potential sources of dietary and non-dietary exposure to the general population such as drinking water and non-occupational exposures, are not expected to be significant or harmful to human health.

E. Cumulative Effects

Since corn gluten is not toxic to mammals, it is unlikely that it will have any cumulative toxic effects when used with other pesticides or substances.

F. Safety Determination

1. *Population in general.* Corn gluten is a non-toxic protein, isolated from corn, a plant used as food by humans and as feed by animals. Corn has been used as food and feed as long as corn has been known to and used by humankind, with no reported adverse effects. Based on this, the Agency believes that the aggregate exposure to corn gluten over a lifetime will not pose appreciable risks to human health. The Agency also concludes that there is a reasonable certainty that no harm will result from aggregate exposure to corn gluten residues and that exempting corn gluten from the requirement of a tolerance is safe.

2. *Infants and children.* Residues of corn gluten pose no potential toxicity to infants and children. Due to the lack of adverse effects and negligible exposure, the Agency concludes with reasonable certainty, that no harm will result to infants and children from aggregate exposure to corn gluten.

G. Existing Tolerances

No tolerances or exemptions from requirements of tolerances have been issued in the United States or internationally for corn gluten.

II. Public Record

The official record for this rulemaking, as well as the public version, has been established for this notice of filing under docket control number [OPP-300505] (including comments and data 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the Virginia address in "ADDRESSES" at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP-300505]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

III. Regulatory Assessment Requirements

This action proposes to establish an exemption from the tolerance requirement under FFDC section 408(e). 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). In addition, this proposed rule 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 28, 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 special 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).

In addition, under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), 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 recordkeeping requirements.

Dated: July 7, 1997.

Janet L. Andersen.

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

Therefore, 40 CFR Chapter I, 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. Section 180.1164 is amended by adding new paragraph (c) to read as follows:

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

* * * * *

(c) Corn gluten is exempt from the requirement of a tolerance on all food commodities when used as an herbicide in accordance with good agricultural practice.

[FR Doc. 97-18973 Filed 7-17-97; 8:45 am]

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