

§ 602.31 Exemptions.

The requirements of this part to make Agency records available do not apply to matters that are:

(a) Specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense or foreign policy and are in fact properly classified pursuant to such Executive Order;

(b) Related solely to the internal personnel rules and practices of the Agency;

(c) Specifically exempted from disclosure by statute;

(d) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(e) Inter-agency or intra-agency memoranda or letters that would not be available by law to a private party in litigation with the Agency;

(f) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(g) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information.

(1) Could reasonably be expected to interfere with enforcement proceedings;

(2) Would deprive a person of a right to a fair trial or impartial adjudication;

(3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(4) Could reasonably be expected to disclose the identity of a confidential source, including a State, local or foreign agency or authority or any private institution that furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(5) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(6) Could reasonably be expected to endanger the life or physical safety of any individual.

(h) Contained in or related to examination, operating or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(i) Geological and geophysical information and data, including maps, concerning wells.

Subpart E—Review of Denials of Records**§ 602.40 Procedure for appealing initial determinations to withhold records.**

(a) A member of the public who has requested an Agency record in accordance with subpart B of this part and who has received an initial determination that does comply fully with the request, may appeal such a determination.

(b) The appeal shall:

(1) Be in writing;

(2) Be initiated within 30 working days of the initial determination denying the request;

(3) Include a copy of the initial written request, a copy of the letter of denial, and the requester's reasons for appealing the denial; and

(4) Be addressed to the Deputy Director, U.S. Arms Control and Disarmament Agency, 320 21st Street, NW., Washington, DC 20451.

(c) The 30-day period for appealing a denial begins on the date of the denial letter. The 30-day limitation may be waived by the Agency for good cause shown. The Agency will consider any request closed if, within 30 working days after a complete or partial denial, the requester fails to appeal the denial.

§ 602.41 Decision on appeal.

(a) Review and final determination on an appeal shall be made by the Deputy Director.

(b) [Reserved]

(c) Review of an appeal shall be made on the submitted record. No personal appearance, oral argument, or hearing shall be permitted.

(d) The final determination on an appeal from a denial shall be made by the Deputy Director within 20 working days of receipt of the appeal by the Agency.

(e) If the final determination is to release the withheld material, the requester will be notified immediately and the material will be forwarded promptly in accordance with the procedure described in § 602.16 for notifications of initial determinations.

(f) If the final determination is to continue to withhold material in whole or in part, the requester will be notified immediately of the determination, the reasons therefore, and the right to judicial review.

(g) All decisions will be indexed and available for inspection and copying in the same manner as other Agency final orders and opinions, if any, under 5 U.S.C. 552(a)(2).

Subpart F—Annual report to the Congress**§ 602.50 Requirements for annual report.**

(a) On or before March 1 of each calendar year, ACDA shall submit a report covering the preceding calendar year to the Speaker of the House of Representatives and the President of the Senate for referral to the appropriate committees of the Congress. The report shall include the following information:

(1) The number of determinations made by ACDA not to comply with requests for records made to the Agency under this part and the reasons for each such determination;

(2) The number of appeals made by persons under subpart E of this part, the result of such appeals, and the reason for the action upon each appeal that results in a denial of information;

(3) The names and titles or positions of each person responsible for the denial of records requested under this part, and the number of instances of participation for each;

(4) The results of each proceeding conducted pursuant to 5 U.S.C. 552(a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

(5) A copy of this part 602 and any other rule or regulation made by ACDA regarding 5 U.S.C. 552;

(6) A copy of the fee schedule and the total amount of fees collected by ACDA for making records available under this part; and

(7) such other information as indicates efforts to administer fully this part.

(b) The FOIA Officer will be responsible for preparing the report for review and submission to the Congress.

Dated: July 15, 1996.

Mary Elizabeth Hoinkes,

General Counsel.

[FR Doc. 96-18884 Filed 8-1-96; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[PP 5E4517/R2270; FRL-5391-4]

RIN 2070-AB78

Phosphinothricin Acetyltransferase (PAT) and the Genetic Material Necessary for Its Production (Plasmid Vector pZ01502) in Corn; Exemption from Requirement of a Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the plant pesticide inert ingredient phosphinothricin acetyltransferase and the genetic material necessary for its production (plasmid vector pZ01502) in corn. A request for an exemption from the requirement of a tolerance was submitted by Northrup King Company (NK). This regulation eliminates the need to establish a maximum permissible level for residues of this plant pesticide inert ingredient in all raw agricultural commodities of field corn, sweet corn, and popcorn.

EFFECTIVE DATE: Effective on August 2, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket number [PP 5E4517/R2270] 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 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 copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, 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.

An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail to: opp-docket@epamail.epa.gov.

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special

characters and any form of encryption. Copies of electronic objections and hearing requests be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 5E4517/R2270]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies electronic 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: Michael L. Mendelsohn, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, U. S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 5th Floor CS, 2800 Crystal Drive, Arlington, VA 22202, (Telephone No. 703-308-8715); e-mail: mendelsohn.michael@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of October 25, 1995 (60 FR 54689)(FRL-4982-4), which announced that Northrup King Company, 7500 Olson Memorial Hwy., Golden valley, MN 55427, had submitted a pesticide petition (PP) 5E4517 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish an exemption from the requirement of a tolerance for the plant pesticide inert ingredient phosphinothricin acetyltransferase (PAT) as produced in corn by the PAT gene and its controlling sequences as found on plasmid vector pZ01502. EPA has assigned the inert ingredient of this product the name phosphinothricin acetyltransferase and the genetic material necessary for its production (plasmid vector pZ01502) in corn. "Genetic material necessary for its production" means the genetic material which comprise (1) genetic material encoding the phosphinothricin acetyltransferase and (2) its regulatory regions. "Regulatory regions" are the genetic material that control the expression of the genetic material encoding the phosphinothricin acetyltransferase, such as promoters, terminators, and enhancers. There were no adverse comments, or requests for referral to an advisory committee received in response to the notice of filing of the pesticide petition 5E4517.

Toxicology Assessment

Data regarding the *in vitro* digestibility of PAT as well as information on the similarity of the PAT enzyme to other proteins were cited and submitted. These data support the prediction that the PAT protein would be non-toxic to humans and have a minimal potential for allergenicity. Residue chemistry data were therefore not required.

The Agency expects that proteins with no significant amino acid homology to known mammalian protein toxins and which are readily inactivated by heat or mild acidic conditions and readily degraded in an *in vitro* digestibility assay have little likelihood for displaying oral toxicity. The *in vitro* digestibility studies indicate that the PAT enzyme would be rapidly degraded following ingestion. Further, the PAT enzyme was shown to have no significant amino acid homology to known mammalian protein toxins.

Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases, are glycosylated and are present at high concentrations in the food. The *in vitro* digestibility studies indicate the PAT protein is rapidly degraded in the gastric environment and is also readily denatured by heat or low pH. Thus, the potential for PAT to be a food allergen is minimal.

The genetic material necessary for the production of PAT are the nucleic acids (DNA) which comprise (1) genetic material encoding the PAT and (2) its regulatory regions. "Regulatory regions" are the genetic material that control the expression of the genetic material encoding PAT, such as promoters, terminators, and enhancers. DNA is common to all forms of plant and animal life and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption. These ubiquitous nucleic acids as they appear in the subject active ingredient have been adequately characterized. Therefore, no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of PAT in corn.

Conclusions

Based on the information considered, the Agency concludes that establishment of a tolerance is not necessary to protect the public health. Therefore, the exemption from tolerance 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 to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed 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 a hearing is requested, the requestor's contentions on such issues, a summary of any evidence relied upon by the objector as well as the other materials required by 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 genuine and substantial issue of fact; there is 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).

EPA has established a record for this rulemaking under docket number [PP 5E4517/R2271] (including any 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 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.

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 rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of 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 comments 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), this action is not a "significant regulatory action" and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Pursuant to the requirements of the Regulatory Flexibility Act (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 statement containing the factual basis for this certification was published in the Federal Register of May 4, 1981 (46 FR 24950).

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a "major rule" as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

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

Dated: July 30, 1996.

Daniel M. Barolo,

Director, 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 subpart D, by adding § 180.1175, to read as

§ 180.1175 Phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production (plasmid vector pZ01502) in corn; exemption from the requirement of a tolerance.

Phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production (plasmid vector pZ01502) in corn is exempt from the requirement of a tolerance when used as a plant pesticide inert ingredient in all raw agricultural commodities of field corn, sweet corn, and popcorn. "Genetic material necessary for its production" means the genetic material which comprise genetic material encoding the phosphinothricin acetyltransferase and its regulatory regions. "Regulatory regions" are the genetic material that control the expression of the genetic material encoding the phosphinothricin acetyltransferase, such as promoters, terminators, and enhancers.

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40 CFR Part 180

[PP 5E4516/R2269; FRL-5391-2]

RIN 2070-AB78

Plant Pesticide Inert Ingredient CP4 Enolpyruvylshikimate-3-D and the Genetic Material Necessary for Its Production in All Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the plant pesticide inert ingredient CP4 Enolpyruvylshikimate-3-D (CP4 EPSPS) and the genetic material necessary for its production in all plants. A request for an exemption from the requirement of a tolerance was submitted by Monsanto Company (Monsanto). This