

Northeast, Redmond, WA 98052, had submitted pesticide petition (PP 4F4334) to EPA proposing that an exemption from the requirement of a tolerance be established for residues of the biochemical growth regulator chitosan when used as a seed treatment on rice.

Chitosan is a naturally occurring substance produced from chitin extracts of crustacean shells (e.g., crab, shrimp, and lobster). The product is intended for use in treatment of seed prior to planting. Plant root growth is stimulated and stem strength enhanced, helping to prevent lodging (when the plants fall over because weak stems are unable to support it) in rice. Plants which lodge are difficult to harvest; therefore, yields may be decreased.

The chemical is taken up by plant cells where it enters the nucleus and stimulates messenger RNA and enzyme production. In the case of rice, such enzymes are thought to be responsible for stimulating the plant to produce more lignin in the stems, resulting in stronger stems and decreased lodging.

The Agency considered the following factors in support of this request for exemption from the requirement of a tolerance: Chitosan (1) is not toxic, as demonstrated in acute toxicity studies in mice, rats, and rabbits; (2) is naturally occurring in the environment in large concentrations; (3) has been exempted from the requirement of a tolerance in or on barley, beans, oats, peas, and wheat (40 CFR 180.1072) when used as a seed treatment at an application rate of 4 oz./100 lbs. seed; (4) has been approved by the State of Oregon for use in unrestricted amounts as a soil amendment (fertilizer), a use not regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act. Certain chitin-based products are permitted to be used in foods as hypocholesterolemic agents, as dietary fiber in low-calorie diets, and as agents to increase the specific loaf volume of bread.

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to this exemption request. Therefore, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request.

Chitosan is considered useful for the purpose for which the exemption from the requirement of a tolerance is sought. Based on the information considered, the Agency concludes that establishment of the exemption will protect the public health. Therefore, the regulation is established as set forth below.

Based on the nontoxic nature of this chemical, the Agency is also establishing an exemption from the requirement of a tolerance for residues of poly-D-glucosamine when used as a pesticide in the production of any raw agricultural commodities.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections and/or request a hearing 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, 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).

Under Executive Order 12866 (58 FR 51735, Oct. 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 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: April 3, 1995.

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. Section 180.1072 is revised to read as follows:

§ 180.1072 Poly-D-glucosamine (chitosan); exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of the biological plant growth regulator poly-D-glucosamine when used as a seed treatment in or on barley, beans, oats, peas, rice, and wheat.

(b) An exemption from the requirement of a tolerance is established for residues of the biological plant growth regulator poly-D-glucosamine when used as a pesticide in the production any raw agricultural commodity.

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