

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

#### List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: March 28, 1995.

**Daniel M. Barolo,**

*Director, Office of Pesticide Programs.*

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[OPP-300381; FRL-4944-1]

#### Propargite; Request for Comment on Petition to Revoke Certain Feed Additive Regulations

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

**ACTION:** Notice; receipt and availability of petition.

**SUMMARY:** This document announces the receipt of and solicits comments on a petition proposing the revocation of the section 409 feed additive regulation established under the Federal Food, Drug and Cosmetic Act (FFDCA, 21 U.S.C. 348a), for propargite on dried apple pomace. This notice sets forth the basis for the petitioner's proposal and provides opportunity for comment by the public.

**DATES:** Written comments, identified by the document control number [OPP-300381], must be received on or before May 19, 1995.

**ADDRESSES:** By mail, requests for copies of the petition and comments should be forwarded to Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Copies of the

petition will be available for public inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays in: Information Services Branch, Program Management and Support Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-305-5805.

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 may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection at the address and hours given above.

**FOR FURTHER INFORMATION CONTACT:** By mail: Niloufar Nazmi, Special Review and Reregistration Division (7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. WF32C5, Crystal Station #1, 2800 Crystal Drive, Arlington, VA, Telephone: 703-308-8028; e-mail: Nazmi.Niloufar@epamail.epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### Introduction

##### A. Statutory Framework

The Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 136 et seq.) authorizes the establishment of tolerances and exemptions from tolerances for the residues of pesticides in or on raw agricultural commodities (RAC's), and section 409 of the act authorizes promulgation of food additive regulations for pesticide residues in processed foods.

Under section 408, EPA establishes tolerances, or exemptions from tolerances when appropriate, for pesticide residues in raw agricultural commodities. Food additive regulations setting maximum permissible levels of pesticide residues in processed foods are established under section 409.

Section 409 food additive regulations are required, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, no section 409 food additive regulation is required if any pesticide residue in a processed food resulting from use on a

RAC has been removed to the extent possible by good manufacturing practices and is below the tolerance for that pesticide in or on that RAC. This exemption in section 402(a)(2) is commonly referred to as the "flow-through" provision because it allows the section 408 raw food tolerance to flow through to processed food. Thus, a section 409 food additive regulation is only necessary to prevent foods from being deemed adulterated when despite the use of good manufacturing practices the concentration of the pesticide residue in a processed food is greater than the tolerance prescribed for the raw agricultural commodity, or if the processed food itself is treated or comes in contact with a pesticide. Monitoring and enforcement are carried out by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

The establishment of a food additive regulation under section 409 requires a finding that use of the pesticide will be "safe" (21 U.S.C. 348(C)(3)). Section 409 also contains the Delaney clause, which specifically provides that, with limited exceptions, no additive may be approved if it has been found to induce cancer in man or animals (21 U.S.C. 348(C)(5)).

In setting both section 408 tolerances and section 409 food additive regulations, EPA reviews residue chemistry and toxicology data. To be acceptable, tolerances must be both high enough to cover residues likely to be left when the pesticide is used in accordance with its labeling and low enough to protect the public health. With respect to section 408 tolerances, EPA determines the highest levels of residues that might be present in a raw agricultural commodity based on controlled field trials conducted under the conditions allowed by the product's labeling that are expected to yield maximum residues. Generally, EPA's policy concerning whether a section 409 food additive regulation is needed depends on whether there is a possibility that the processing of a raw agricultural commodity containing pesticide residues would result in residues in the processed food at a level greater than the raw food tolerance.

#### II. Petitions

Uniroyal Chemical Co. has submitted a petition requesting the revocation of the feed additive regulation (FAR) established under section 409 of the FFDCA for propargite on dried apple pomace. This regulation is codified in 40 CFR 186.5000 and is established at 80 parts per million (ppm).