

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: January 17, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner's summaries of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summaries of the petitions were prepared by the petitioner and represent the views of the petitioner. The petitions summaries announce the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemicals residues or an explanation of why no such method is needed.

Valent U.S.A. Corporation

PP 8F3591 and PP 9F3798

EPA has received pesticide petitions (8F3591 and 9F3798) from Valent U.S.A. Corporation, 1333 North California Boulevard, Suite 600, Walnut Creek, California 94596-8025 proposing, pursuant to section 408(d) of

the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.432 by establishing tolerances for residues of the herbicide lactofen, 1-(carboethoxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate, in or on the raw agricultural commodities (RACs) cottonseed at 0.01 part per million (ppm), cotton gin byproducts at 0.02 ppm, and peanut nutmeats at 0.01 ppm. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism.* The nature of the residue in plants is adequately understood based on plant metabolism studies on cotton, peanut, soybean, and tomato. The Health Effects Division (HED) Metabolism Assessment Review Committee (MARC) met on April 4, 2000, considered all of the metabolism studies submitted to date and concluded that only the parent compound needs to be regulated for plant commodities, provided that pre-harvest intervals exceed 45 days.

2. *Analytical method.* Adequate analytical methodology is available for detecting and measuring levels of lactofen in or on RACs with a limit of detection (LOD) that allows monitoring of food with residues at or above the level of the proposed tolerances. The method, RM-28D, has been successfully radio validated in conjunction with a tomato metabolism study and has undergone a successful independent laboratory validation trial. This method was also successfully validated by EPA's Analytical Chemistry Laboratory using peanut nutmeats and cottonseed. In general, the analytical method has a LOD of 0.005 ppm and limit of quantitation (LOQ) of 0.01 ppm in crops.

3. *Magnitude of residues.* Adequate lactofen residue data are available for cotton and peanuts. An adequate number of field trials distributed throughout cotton and peanut growing areas of the United States have been conducted on these crops to determine lactofen residues resulting from the application of lactofen at the maximum labeled or proposed use rate.

i. *Cotton.* Residues of lactofen were each <0.01 ppm, in/on cottonseed (n=14) harvested 59-127 days following a single postemergence soil-directed application of lactofen at 0.4 lb active

ingredient per acre (lb active ingredient/acre) (2x the single application rate) and in/on cottonseed (n=10) harvested 23-108 days following the last of two postemergence directed applications at 0.4 lb active ingredient/acre application (2x the maximum seasonal rate). With one exception, residues of lactofen were also each <0.01 ppm, in/on cotton gin byproducts (gin trash) (n=11) derived from cotton harvested 69-108 days following two applications at 0.2 lb active ingredient/acre. One gin trash sample bore residues of lactofen at 0.03 ppm, but confirmatory analyses of this sample detected lactofen at <0.01-0.02 ppm, and residues of lactofen were <0.01 ppm, in the duplicate treated sample from the same trial.

In a single processing study, residues of lactofen were <0.01 ppm, in/on cottonseed harvested 76 days following the last of two directed applications of lactofen at 0.6 lb active ingredient/acre application (1.2 lb active ingredient/acre/season, 3x rate). Residues of lactofen were <0.01 ppm in samples of meal, hulls, oil, (crude and refined) and soapstock.

All these data support proposed tolerance for lactofen in/on cottonseed at 0.01 ppm, and in/on cotton, gin byproducts at 0.02 ppm. No separate tolerances are needed for cotton processed commodities.

ii. *Peanuts.* In 8 field trials, residues of lactofen were each <0.01 ppm, in/on 16 samples of peanut nutmeats and hulls harvested 65-71 days following the last of 2 broadcast applications of lactofen totaling 0.45 lb active ingredient/acre (1x the maximum proposed rate). Residues of lactofen were also <0.01 ppm, in/on peanut nutmeats and hulls from 2 trials conducted at 2x and 5x the maximum seasonal rate.

In a processing study, residues of lactofen were <0.01 ppm in meal, oil, crude and refined, and soapstock processed from nutmeats treated at 3x and 5x the maximum proposed use rates.

All these data support proposed tolerance for lactofen in/on peanut nutmeats at 0.01 ppm. No separate tolerances are needed for peanut processed commodities.

B. Toxicological Profile

1. *Acute toxicity.* Lactofen has very low acute toxicity. The acute oral LD₅₀ is 5.96 gram/kilogram/body weight (g/kg/bwt) toxicity category IV, the acute dermal LD₅₀ is >2.0 g/kg/bwt toxicity category III and the acute inhalation LD₅₀ is >6.3 milligrams/liter (mg/L) toxicity category IV. Lactofen is not a