

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 FARs, EPA reviews residue chemistry and toxicology data. To be acceptable, tolerances and FARs 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 an RAC 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 FAR is needed depends on whether there is a possibility that the processing of an RAC containing pesticide residues would result in residues in the processed food at a level greater than the raw food tolerance. EPA makes these determinations based on processing studies.

## II. International Apple Institute Petition

The International Apple Institute (IAI) has submitted a petition requesting the revocation of the FAR established under section 409 of the FFDCA for residues of benomyl, propargite, thiophanate-methyl, and triadimefon in dried apple pomace. The FARs for residues of benomyl, propargite, thiophanate-methyl, and triadimefon in dried apple pomace are codified in 40 CFR 186.350, 186.5000, 186.5700, and 186.800, respectively.

### Background

EPA requires processing data and sets tolerances and FARs only on animal feeds that are consumed in significant amounts in the United States. Table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, provides a listing of all significant food and feed commodities, both raw and processed, for which residue data are collected and tolerances or FARs are established. On September 21, 1995, EPA announced the availability of the updated Table II and modified its guidelines regarding which raw commodities and processing byproducts EPA will consider as animal feeds requiring FARs (60 FR 49150). The general cutoff point used by EPA in deciding which feed items are considered "significant", is whether the feed item constitutes greater than 0.04 percent, by weight, of the total feed available to livestock in the U.S.

Based on the above criteria, the Agency has determined that dried apple pomace is not a significant feed item and has removed it from Table II. Subsequently, in the Federal Register of September 21, 1995 (60 FR 49141), EPA issued a proposed rule to revoke the FARs for residues of benomyl, propargite, thiophanate-methyl, and triadimefon in dried apple pomace.

## III. Janssen Pharmaceutica Petition

Janssen Pharmaceutica is petitioning EPA to revoke the section 409 FAR for imazalil in citrus oil on the grounds that, in the ready-to-eat form, the residue levels are below the section 408 tolerance level established for imazalil in the RAC. The Petitioner argues that by the virtue of the flow-through provision of section 402(a)(2) of the FFDCA, the FAR is unnecessary. The FAR for residues of imazalil in citrus oil is codified in 40 CFR 185.3650.

The Petitioner maintains that citrus oil is used as a flavoring agent in minuscule amounts, and if used in excess, it renders food unpalatable. Included in the petition is a survey of flavoring ingredient usage levels conducted by the Flavoring Extract Manufacturers' Association. These values allegedly represent the quantity of citrus oil added to food to accomplish its intended physical effect. The data presented show that maximum residues of imazalil in ready-to-eat foods are below the section 408 tolerance. Therefore, Janssen Pharmaceutica argues that the section 409 FAR is not needed and should be revoked on the basis that it is not necessary.

### Background

In the Federal Register of January 18, 1995 (60 FR 3607), EPA issued a proposed rule to revoke the section 409 FAR for imazalil in citrus oil because the Agency has determined that imazalil induces cancer in animals and therefore violates the Delaney clause in section 409 of the FFDCA.

In the Federal Register of June 14, 1995 (60 FR 31300), EPA issued its response to a petition filed by the National Food Processors Association that sought the revision of many EPA policies. In that notice, EPA announced its revised approach to the term ready-to-eat (RTE). EPA believes that a food should be considered ready to eat only if it is consumed "as is" or added to other ready-to-eat foods. If EPA finds that a processed food form is not ready to eat, and once diluted to its RTE form the residues are below that of the RAC, then a section 409 FAR would not be needed and the Delaney clause would not apply. The Agency's final rule

regarding the residues of imazalil in citrus oil will be published by July 1996.

## IV. Mancozeb Task Force Petition

The Mancozeb Task Force (DuPont, Elf Atochem North America, Inc., and Rohm & Haas Co.) has submitted a petition requesting the revocation of the FARs established under section 409 of the FFDCA for residues of mancozeb in or on milled feed fractions of barley, oats, rye, and wheat. This FAR is codified in 40 CFR 186.6300.

As explained in section II above, EPA recently updated Table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry. EPA has determined that milled fractions of barley, oats, and rye are not significant feed items, and therefore the section 409 FAR is no longer necessary. In the Federal Register of September 21, 1995 (60 FR 4915), EPA issued a proposed rule to revoke the FAR for residues of mancozeb on milled fractions of barley, oats, and rye.

As explained in section III above, on June 14, 1995, EPA announced its revised approach to the term ready-to-eat. Based on this policy, EPA has determined that milled fractions of wheat is not a ready-to-eat feed item, and once diluted, the residues of mancozeb in the RTE animal feeds are unlikely to exceed the section 408 tolerance level. Therefore, a section 409 FAR is unnecessary. On this basis, in the Federal Register of September 21, 1995 (60 FR 49150), EPA revoked the section 409 FAR on milled fractions of wheat.

Pursuant to 40 CFR 177.125 and 177.30, EPA may issue an order ruling on the petitions or may issue a proposal in response to the petitions and seek further comment. If EPA issues an order in response to the petitions, any person adversely affected by the order may file written objections and a request for a hearing on those objections with EPA on or before the 30th day after date of the publication of the order (40 CFR 178.20).

A record has been established for this notice under docket number [OPP-300404] (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 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,