# ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300415; FRL-5351-6]

RIN 2070-AB18

# Pesticide Tolerances; Proposed Revocations

**AGENCY:** Environmental Protection

Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA announces its decision on whether to propose revocation of 41 section 408 tolerances for 22 pesticides. Under EPA's policy concerning the coordination of its authorities under sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA), EPA proposes to revoke the following nine section 408 tolerances: dicofol on apples, grapes, and plums; mancozeb on oats and wheat; propargite on apples and figs; simazine on sugarcane; and triadimefon on wheat. These proposed revocations are one of a series of actions being taken in response to a decision of the Ninth Circuit Court of Appeals regarding the Delaney clause in section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). EPA proposes to leave the remaining tolerances in place. DATES: Written comments, identified by the docket number [OPP-300415], must be received on or before May 30, 1996. ADDRESSES: By mail, submit comments to: Public Response Section, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: OPP Docket, Public Information Branch, Field Operations Division, Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The telephone number for the OPP docket is (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 and in section 10 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). For questions related to disclosure of materials, contact the OPP Docket at the telephone number given above. 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 in the OPP Docket, Rm. 1132 at the Virginia address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-300415]. No CBI should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in [OPP-300415]. of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Niloufar Nazmi, Special Review and Reregistration Division (7508W), Environmental Protection Agency, 401 M St. SW., Washington, DC, 20460. Office location and telephone number: Crystal Station #1, 2800 Crystal Drive, Arlington, VA. Telephone 703–308–8028, nazmi@niloufar@epamail.epa.gov. SUPPLEMENTARY INFORMATION:

#### **Table of Contents:**

- I. Introduction
- II. Background
  - A. Statutory Background
- B. EPA's Policy Concerning Coordination of Its Authorities Under Sections 408 and 409 of the FFDCA
  - C. Regulatory Background
  - III. Today's Action
- IV. Determination of the Need for a Section 409 FAR
- A. Pesticide Uses that Do Not Need a Section  $409~\mathrm{FAR}$
- B. Pesticide Uses Previously Found Not to Need Any Section 409 FARs
- C. Additional Pesticide Uses Found Not to Need Any Section 409 FARs
- D. Pesticide Uses that Need a Section 409 FAR
- V. Delaney Clause Determinations for Needed Section 409 FARs
  - VI. Proposed Revocations
  - VII. Consideration of Comments
  - VIII. Public Docket
  - IX. Regulatory Requirements

## I. Introduction

In this notice, EPA announces its decision whether 41 section 408 tolerances for 22 pesticides should be revoked under EPA's policy concerning the coordination of its authorities under sections 408 and 409 of FFDCA. For those tolerances that EPA has determined should be revoked, EPA is in this notice proposing revocation.

#### II. Background

### A. Statutory Background

The Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 301 et seq.) authorizes the establishment of maximum permissible levels of pesticides in foods, which are referred to as "tolerances" (21 U.S.C. 346a, 348). Without such a tolerance or an exemption from a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce (21 U.S.C. 342). Monitoring and enforcement of pesticide residues are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

The FFDCA governs tolerances for raw agricultural commodities (RACs) and processed foods separately. For pesticide residues in or on RACs, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408. For processed foods, food additive regulations (FARs) setting maximum permissible levels of pesticide residues are established under section 409. Section 409 FARs are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, no section 409 FAR is required for pesticide residues carrying from raw to processed food if the residue in the processed food, when ready to eat, is equal to or below the section 408 tolerance for that pesticide in or on the RAC from which it was derived, and all other conditions of section 402(a)(2) are met. This exemption in section 402(a)(2) is commonly referred to as the "flowthrough" provision because it allows the section 408 raw food tolerance to flow through to the processed food form. Thus, a section 409 FAR is necessary to prevent foods from being deemed adulterated when the concentration of the pesticide residue in a processed food carrying over from the RAC is greater than the tolerance prescribed for the RAC, or if the processed food itself is treated or comes in contact with a

To establish a tolerance regulation under section 408, EPA must find that the regulation would "protect the public health." 21 U.S.C. 346a(b). In reaching this determination, EPA is directed to consider, among other things, the "necessity for the production of an adequate, wholesome, and economical food supply." Id. If a food additive regulation must be established, section 409 of the FFDCA requires that the 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 little exception, "no additive shall be deemed safe if it has been found to induce cancer when ingested by man or animal" (21 U.S.C. 348(c)(3)).

B. EPA's Policy Concerning Coordination Of Its Authorities Under Sections 408 and 409 of the FFDCA

EPA traditionally has followed a policy of coordinating its authorities under section 408 and section 409 of the FFDCA. Thus, if use of a pesticide would result in residues in a RAC needing a section 408 tolerance and residues in a processed food needing a section 409 FAR, EPA would not approve either the section 408 tolerance or the section 409 FAR if EPA could not approve both. Similarly, EPA would not approve a FIFRA registration for a use of a pesticide if all needed tolerances and FARs connected with that use could not be approved.

In September 1992, the National Food Processors' Association (NFPA) and other food-related organizations filed a petition with EPA challenging the legality of EPA's coordination policy. In a policy statement issued on January 25, 1996, (61 FR 2378) EPA for the most part rejected the NFPA's arguments concerning the coordination policy. EPA will continue to coordinate its actions under sections 408 and 409. Where a pesticide needs a section 409 FAR but such FAR cannot be granted because of the Delaney clause, EPA generally will not grant, or allow to continue, the associated section 408

The critical issue in the application of the coordination policy is whether there is a likelihood of residues exceeding the section 408 tolerance in ready-to-eat (RTE) processed food. If there is such a likelihood of over-tolerance residues, EPA believes it is a reasonable interpretation of section 408 to conclude that the section 408 tolerance does not meet the statutory standard under section 408 ("protect the public health") and thus must be revoked. The criteria EPA follows in determining the likelihood that residues in processed food will exceed the section 408 tolerance are called the concentration policy. Until recently, EPA's concentration policy had focused almost entirely on the results of food processing studies and concentration factors derived from those studies. Concentration factors measure the ratio between residue levels in the processed food and the precursor raw crop (e.g., a concentration factor of 2 indicates that residues in the processed food are twice the level of residues in the raw crop).

However, in responding to the NFPA petition on June 14, 1995 (60 FR 31300), EPA announced it would consider a far greater range of information in making the determination concerning the likelihood of residues in processed food exceeding the section 408 tolerance.

#### C. Regulatory Background

1. Les v. Reilly. On May 25, 1989, the State of California, the Natural Resources Defense Council (NRDC), Public Citizen, the AFL-CIO, and several individuals filed a petition requesting that EPA revoke several food additive regulations. The petitioners argued that these food additive regulations should be revoked because they violated the Delaney clause.

EPA responded to the petition by revoking certain food additive regulations, but retained several others on the grounds that the Delaney clause provides an exception for pesticide residues posing de minimis risk; EPA denied the petition with respect to the food additive regulations determined to fall under this exception. EPA's response was challenged by the petitioners in the U.S. Court of Appeals, Ninth Circuit. On July 8, 1992, the court ruled in Les v. Reilly, 968 F.2d 985 (9th Cir.), cert. denied, 113 S.Ct. 1361 (1993), that the Delaney clause barred the establishment of a food additive regulation for pesticides which "induce cancer" no matter how infinitesimal the risk. In response to the court's decision in Les v. Reilly, EPA has taken steps to identify and revoke all section 409 FARs for pesticides which "induce cancer." On March 30, 1994, EPA issued a list of pesticide uses which potentially could be affected by the court's decision. (59 FR 14980) (Note that, for the purpose of today's document, this list has been superseded by Appendices to the courtapproved settlement in California v. Browner.) EPA has taken the following actions in response to Les v. Reilly:

(1) Revoked certain FARs of six pesticides that were the subject of the original NRDC petition. (58 FR 37862, July 14, 1993; 58 FR 59663, November 10, 1993; and 59 FR 10993, March 9, 1994-a number of these actions have been challenged in court or have been

stayed).

(2) Proposed to revoke 26 FARs for seven pesticides (59 FR 33941, July 1, 1994)

- (3) Proposed to revoke six FARs for four pesticides (60 FR 3607, January 18,
- (4) Proposed to revoke two FARs for two pesticides as inconsistent with the Delaney clause and proposed to revoke 34 other FARs for 16 pesticides because the FARs were not needed to prevent

the adulteration of food (60 FR 49142, September 21, 1995).

Having completed review (at least through the stage of issuing a proposed action) of the section 409 FARs identified as potentially inconsistent with the Delaney clause, EPA, in this notice, has focused its attention on the application of the coordination policy to the section 408 tolerances. Specifically, EPA is focusing on the section 408 tolerances associated with the section 409 FARs considered in the July 1994, January 1995, and September 21, 1995 notices, as well as several other section 408 tolerances identified previously as potentially affected by EPA's coordination policy. Today's notice announces decisions on 41 section 408 tolerances of 22 pesticides. These pesticides are summarized in Table 1 of Unit III of this document. EPA is proposing to revoke 9 section 408 tolerances for 5 pesticides and is proposing not to revoke the remaining 31 section 408 tolerances. The one remaining section 408 tolerance was previously revoked.

2. California v. Browner. In a court approved settlement, entered on February 9, 1995, in the case of California v. Browner, EPA agreed to make decisions regarding pesticides that may be affected by the Delaney clause. This settlement agreement includes appendices listing pesticides and uses upon which EPA must make decisions, and a timetable for making the decisions. The settlement required EPA to rule on the NFPA petition that challenged a number of policies under which EPA administers its tolerancesetting program. This proposal complies with the timeframes in the California v.

Browner settlement.

On June 14, 1995, EPA published a partial response to the NFPA petition (60 FR 31300). The Agency concluded that some changes were warranted to its policies concerning application of the Delaney clause. On January 25, 1996 (61 FR 2378) EPA completed its response to the NFPA petition by reaffirming its coordination policy. Today's proposals are in accordance with EPA's responses to the NFPA petition.

#### III. Today's Action

In the California v. Browner settlement, EPA agreed to make decisions by April, 1997 concerning whether 81 section 408 tolerances violated EPA policies regarding the coordination of its authority under sections 408 and 409. The settlement recognized that these policies might be modified by EPA's response to the NFPA petition. Today's notice announces EPA's decisions regarding 41 of those tolerances (See Table 1 of this document.) EPA has treated the California v. Browner consent decree as the equivalent of a petition under section 408(e) requesting the reexamination of the legality, under the coordination policy, of the tolerances listed in the appendices to the decree. This notice, in effect, acts on the petition by proposing revocation of those tolerances that EPA has determined do not meet the statutory standard under section 408 and by proposing not to initiate a revocation proceeding against those tolerances to which EPA has found the coordination policy is inapplicable. EPA is seeking comment on both the proposed revocations and its proposed decisions not to revoke and will issue a final order following the receipt and review of such comments.

TABLE 1.—SECTION 408 RAW FOOD TOLERANCES IN THIS NOTICE.

Pesticide	Crop	CFR Cite	Pro- posed Deci- sions
Acephat- e.	Cottonseed	180.108	Retain
Alachlor .	Sunflower seed.	180.249	Pre- vious- ly re- voked
Benomyl	Citrus	180.294	Retain
	Rice	180.294	Retain
Captan	Grapes	180.103	Retain
	Tomatoes	180.103	Retain
Carbaryl	Pineapples .	180.169	Retain
Dicofol	Apples	180.163	Revoke
	Grapes	180.163	Revoke
	Plums	180.163	Revoke
	Tomatoes	180.163	Retain
Difluben- zuron.	Soybeans	180.377	Retain
Dimethi- pin.	Cottonseed	180.406	Retain
Ethylene Oxide.	Whole spices (direct treatment).	180.151	Retain
Iprodione	Peanuts	180.399	Retain
	Rice	180.399	Retain
Lindane .	Tomatoes	180.133	Retain
Mancoz- eb.	Barley	180.176	Retain
	Grapes	180.176	Retain
	Oats	180.176	Revoke
	Rye	180.176	Retain
	Wheat	180.176	Revoke
Maneb	Grapes	180.110	Retain
Methom- yl.	Wheat	180.253	Retain
Norflura- zon.	Grapes	180.356	Retain

TABLE 1.—SECTION 408 RAW FOOD concentration policy. EPA applies the TOLERANCES IN THIS NOTICE.—Continued

Pesticide	Crop	CFR Cite	Pro- posed Deci- sions
Oxyfluor- fen.	Cottonseed	180.381	Retain
	Peppermint	180.381	Retain
	Spearmint	180.381	Retain
	Soybeans	180.381	Retain
PCNB	Tomatoes	180.319	Retain
Permeth- rin.	Tomatoes	180.378	Retain
Propargi- te.	Apples	180.259	Revoke
	Figs	180.259	Revoke
	Grapes	180.259	Retain
	Plums	180.259	Retain
Simazine	Sugarcane .	180.213	Revoke
Thiodica- rb.	Cottonseed	180.407	Retain
	Soybeans	180.307	Retain
Triadime- fon.	Grapes	180.410	Retain
	Wheat	180.410	Revoke
	Pineapple	180.410	Retain

In reviewing these 41 section 408 tolerances under its coordination policy, EPA's first step was to determine whether the section 409 FARs for such tolerances were needed. If a section 409 FAR is not needed in connection with a section 408 tolerance, the coordination policy would not be triggered because it only addresses the appropriate action to be taken where approvals are needed under both sections 408 and 409.

If EPA determined that a section 409 FAR is needed, EPA then determined whether a section 409 FAR for the pesticide in question would comply with the Delaney clause. If a needed section 409 FAR would violate the Delaney clause, EPA applied its coordination policy and has, where appropriate, proposed in this notice the revocation of each section 408 tolerance for which the Delaney clause bars the establishment or maintenance of a section 409 FAR.

### IV. Determination of the Need For a Section 409 FAR

Because the coordination policy has no application to section 408 tolerances that do not need section 409 FARs, EPA has first examined whether each of the 41 section 408 tolerances need FARs under current Agency policies. The determination whether a section 409 FAR is needed to prevent a food from being considered adulterated primarily involves application of EPA's

concentration policy to examine the likelihood that use of a pesticide on a raw agricultural commodity will result in residues in a processed food exceeding the section 408 tolerance.

### A. Pesticide Uses that Do Not Need a Section 409 FAR

EPA has determined that its coordination policy does not warrant revoking 31 of the 41 section 408 tolerances because no section 409 FAR is needed for these tolerances. EPA has concluded that section 409 FARs are not needed principally for one of three reasons. First, for several pesticide/ processed food combinations, EPA has received new processing studies indicating that residues in processed food are not likely to exceed the section 408 tolerance. Second, application of EPA's new concentration policy has shown that, for several of the pesticide uses, residues in processed food are not likely to exceed the section 408 tolerance. Third, several processing byproducts have been dropped from EPA's list of significant animal feed items and therefore FARs are no longer needed for these processed commodities. See 60 FR 49144.

In a proposed revocation published September 21, 1995 (60 FR 49142), EPA explained which of these factors applied to several of the section 409 FARs associated with section 408 tolerances addressed in this notice. Those FARs are listed in this unit with a crossreference to the earlier notice. EPA has also evaluated additional pesticide uses having section 408 tolerances to determine where section 409 FARs would be needed. This notice includes explanations of EPA's conclusions regarding whether section 409 FARs are, or are not needed. A fuller explanation as to each pesticide use is included in the public docket.

### B. Pesticide Uses Previously Found Not to Need Any Section 409 FARs

On September 21, 1995, EPA proposed to revoke the following FARs on the ground that no section 409 FAR was needed to prevent processed food from being considered adulterated: (1) Acephate on cottonseed hulls and cottonseed meal; (2) benomyl on dried citrus pulp and rice hulls; (3) carbaryl on pineapple bran; (4) diflubenzuron on soybean hulls and soybean soapstock; (5) dimethipin on cottonseed hulls; (6) iprodione on peanut soapstock, rice bran and rice hulls; (7) mancozeb on milled fractions of barley, oats, rye and wheat; (8) propargite on dried apple pomace and dried grape pomace; (9) thiodicarb on cottonseed hulls and

soybean hulls; and (10) triadimefon on wet and dry grape pomace and raisin waste. 60 FR 49142, September 21, 1995).

Based on these determinations, EPA concludes that the following 10 section 408 tolerances have or need no other section 409 FARs and thus there is no reason under the coordination policy to revoke these tolerances: (1) Acephate on cottonseed; (2) benomyl on citrus; (3) carbaryl on pineapple; (4) diflubenzuron on soybeans; (5) dimethipin on cottonseed, (6) iprodione on peanuts and rice; (7) thiodicarb on cottonseed and soybeans; and (8) triadimefon on grapes.

It should be noted that unless all needed section 409 FARs can be approved, EPA will apply the coordination policy to revoke the underlying section 408 tolerance for the RAC. This means that even if EPA can determine that one section 409 FAR is not needed by application of the factors noted above, but other section 409 FARs continue to be needed, the coordination policy applies. For example, in the list above, propargite no longer requires a FAR on dried apple pomace because it is not a significant animal feed, but does require a FAR on wet apple pomace. Since the FAR on wet apple pomace is needed and violates the Delaney clause (see Unit IV.D. of this document), EPA is proposing to revoke the section 408 tolerance for propargite on apples.

- C. Additional Pesticide Uses Found Not to Need Any Section 409 FARs
- 1. Recent processing studies— a. oxyfluorfen on soybeans. This use has a section 409 FAR for soybean oil. Based on a new processing study, EPA has determined that the concentration factor for oxyfluorfen residues in soybean oil compared to soybeans is less than one. Therefore, EPA concludes that residues in soybean oil are unlikely to exceed the section 408 tolerance and no section 409 FAR is needed for soybean oil. Oxyfluorfen on soybeans has or needs no other section 409 FARs.
- b. Benomyl on rice. This use was previously identified as needing a section 409 FAR for rice bran. Based on a new processing study, EPA has determined that the concentration factor for benomyl residues in rice bran compared to rice is less than one. Therefore, no section 409 FAR is needed for rice bran. As noted above, EPA determined in the September 1995 notice that no section 409 FAR is needed for benomyl on rice hulls. Benomyl on rice has or needs no other section 409 FARs.
- c. Propargite on plums. This use was previously identified as needing a

- section 409 FAR for prunes. Based on a new processing study, EPA has determined that the concentration factor for propargite on prunes compared to plums is less than one. Therefore, no section 409 FAR is needed for prunes. Propargite on plums has or needs no other section 409 FARs.
- 2. Revised concentration policy. EPA's concentration policy is used to determine whether a section 409 FAR is necessary. EPA's determination focuses on the likelihood that residue levels in the processed food will exceed the associated section 408 tolerance level. In determining the likelihood of tolerance exceedance, EPA now considers the averaging of residue values that results from the blending of crops (highest average field trial or HAFT), average concentration factor (from multiple processing studies), and the dilution of residues that occurs when a not ready-to-eat processed food is made into ready-to-eat food. Below EPA explains which of those factors resulted in the determination that section 409 FARs are not needed for the following section 408 tolerances.
- a. Captan on grapes. This use has section 409 FARs for pre-harvest treatment of grapes and post-harvest treatment of raisins.

Pre-harvest treatment of grapes. EPA has reconsidered the available grape/ raisin processing studies and has determined that only those studies that involve washing the fruit after it has been dried in the field reflect current processing practices. When those data which include a washing step were used to evaluate the need for a section 409 FAR for raisins, the average concentration factor for residues of captan per se on washed raisins is less than one. Therefore, no section 409 FAR is needed for residues from pre-harvest treatment. The Captan Task Force has petitioned EPA to revoke the section 409 FAR to the extent it is premised on pre-harvest treatment of grapes and EPA will be acting on that petition shortly.

Post-harvest treatment of raisins. EPA has received a petition from the Captan Task Force requesting revocation of the section 409 FAR covering the post-harvest treatment of raisins because, they claim, captan is not used on drying raisins and the FAR is outdated and erroneous. EPA agrees with the Petitioner and will shortly publish its formal determination that no FAR is needed for post-harvest treatment in a final rule.

Grape juice. After examining 17 processing studies, EPA has determined that the average concentration factor in juice is less than one. Therefore, this

FAR is not needed. Captan on grapes has or needs no other section 409 FARs.

b. *Mancozeb on barley and rye*. There are section 409 FARs for residues of mancozeb on bran, flour and milled fractions as an animal feed.

Flours of barley and rye. After examining several processing studies involving mancozeb residues on grains, EPA has determined that the average concentration factor for the processing of flours is less than one. Therefore, the section 409 FARs are not needed for these flours.

Brans of barley and rye. The use of mancozeb on barley and rye have section 409 FARs for bran. On May 19, 1993, EPA published the receipt of a petition requesting the revocation of brans of barley and rye on the basis that they are not needed (58 FR 29318). EPA has determined that rye bran is not a significant human food item. EPA has also determined that both rye and barley bran are not RTE foods and that once they are prepared to their RTE forms, mancozeb residues are unlikely to exceed the section 408 tolerances for rye and barley grains. Therefore, the section 409 FARs for mancozeb on brans of barley and rye are not needed and EPA will soon be publishing a Federal Register notice revoking them.

Mancozeb on barley and rye has or needs no other section 409 FARs.

- c. Methomyl on wheat. This use does not have a section 409 FAR for wheat bran but was previously identified as needing one. EPA has multiplied the HAFT by the average concentration factor to calculate the expected residue levels in bran. The data show that residues in bran are not likely to significantly exceed the section 408 tolerance and therefore a section 409 FAR for bran is not required. Methomyl on wheat has or needs no other section 409 FARs.
- d. Oxyfluorfen on cottonseed, peppermint, and spearmint. The uses of oxyfluorfen on cottonseed, peppermint, and spearmint have section 409 FARs for oils produced from these crops. EPA has determined that cottonseed oil, peppermint oil, and spearmint oils are not RTE human foods and once in their RTE forms, the residues of oxyfluorfen are unlikely to exceed the section 408 tolerances. EPA will soon be acting on a petition requesting revocation of these FARs on these grounds. Oxyfluorfen on cottonseed, peppermint, and spearmint have or need no other section 409 FARs.

The Agency believes that most refined oils (e.g., soybean oil, olive oil) should be considered RTE commodities based on their availability to the general public in typical grocery stores and subsequent use on salads. The latter use

is very similar to condiments, which the Agency noted in its June 1995 response to the NFPA petition should be considered RTE foods. In this notice, EPA for the first time makes a RTE determination for cottonseed oil. Unlike most other refined oils, cottonseed oil has very limited availability in grocery stores. The National Cottonseed Products Association (NCPA) has estimated that only 0.1% of all U.S. cottonseed oil production is sold at the grocery store level. NCPA has informed the Agency that most cottonseed oil is used by the snack food industry. As an example, it is a good frying medium for production of potato chips. Based on its almost exclusive use by the food processing industry, the Agency has determined that cottonseed oil is not ready to eat. As noted above, EPA believes that most other refined oils should be considered ready to eat. The Agency is requesting public comment and information on whether oils such as soybean, peanut, olive and corn should be considered ready to eat.

e. Propargite on grapes. This use has a section 409 FAR for raisins. EPA has multiplied the HAFT by the average concentration factor to calculate the expected residue levels in raisins. The data show that residues in raisins are not likely to exceed the section 408 tolerance for grapes and therefore a section 409 FAR is not needed. EPA will soon be publishing a Federal Register notice revoking this FAR. The section 409 FAR for dry grape pomace was proposed for revocation in September 21, 1995. Propargite on grapes has or needs no other section 409 FARs.

3. Insignificant animal feeds. As explained above, several processing byproducts (including tomato pomace, dried grape pomace, and raisin waste) have been dropped from EPA's list of significant animal feed items and therefore their section 409 FARs are not needed. Table 2 of this unit lists section 408 tolerances with the corresponding animal feeds that do not need section 409 FARs: (1) Captan on grapes does not need a raisin waste FAR; (2) captan on tomatoes does not need a dry tomato pomace FAR; (3) dicofol on grapes does not need a dry grape pomace or a raisin waste FAR; (4) dicofol on tomatoes does not need a dry/wet tomato pomace FAR; (5) lindane on tomatoes does not need a dry tomato pomace FAR; (6) mancozeb on grapes does not need a raisin waste FAR; (7) maneb on grapes does not need a raisin waste FAR; (8) norflurazon on grapes does not need a raisin waste FAR; (9) PCNB on tomatoes does not need a dry tomato pomace FAR; (10) permethrin on tomatoes does not need dry/ wet tomato pomace FAR; and

(11)Propargite on grapes does not need a raisin waste FAR. If no other section 409 FARs are needed, the coordination policy does not require revocation of the section 408 tolerances.

4. Other— a. Alachlor on sunflower seeds. This tolerance was revoked on August 3, 1994 (59 FR 39464).

b. Ethylene oxide on raw whole spices. Ethylene oxide is used as direct treatment of raw whole spices and processed ground spices. Ethylene oxide has both a section 408 tolerance (raw whole spices) and a section 409 FAR (processed ground spices). The FAR, however, is needed only for direct treatment of processed ground spices and not because of any concern that treatment of raw whole spices will lead to residues in processed spices at a level exceeding the section 408 tolerance. The residues of ethylene oxide in processed ground spices from treatment of whole raw spices are not expected to exceed the section 408 tolerance.

c. Triadimefon on pineapple. Pure pineapple bran is no longer considered a significant feed item and has been dropped from the list of significant feed items in the Agency's Residue Chemistry Guidelines. However, EPA has added pineapple process residue to this table of significant feed items because the Agency has determined that the material typically fed to livestock is pineapple process residue. This feed item consists of tops (minus crowns), bottoms, trimmings, pulp (remaining after squeezing for juice), and, in some cases, cull pineapples. Since the processing study for triadimefon in pineapples shows that residues do not concentrate in the process residue, a section 409 FAR is not needed. Triadimefon on pineapple has or needs no other section 409 FARs.

Table 2 below summarizes the section 408 raw food tolerances that EPA is not proposing to revoke under its coordination policy.

TABLE 2.—SECTION 408 RAW FOOD TOLERANCES BEING PROPOSED FOR RETENTION

	Raw commodity	
Pesticide	Crop	CFR cite
Acephate	Cottonseed .	180.108
Benomyl	Citrus	180.294
	Rice	180.294
Captan	Grapes	180.103
	Tomatoes	180.103
Carbaryl	Pineapples	180.169
Dicofol	Tomatoes	180.163
Diflubenzuron	Soybeans	180.377

TABLE 2.—SECTION 408 RAW FOOD TOLERANCES BEING PROPOSED FOR RETENTION—Continued

	Raw commodity	
Pesticide	Crop	CFR cite
Dimethipin	Cottonseed .	180.406
Ethylene Oxide	Whole spices (di- rect treat- ment).	180.151
Iprodione	Peanuts	180.399
	Rice	180.399
Lindane	Tomatoes	180.133
Mancozeb	Barley	180.176
	Grapes	180.176
	Rye	180.176
Maneb	Grapes	180.110
Methomyl	Wheat	180.253
Norflurazon	Grapes	180.356
Oxyfluorfen	Cottonseed .	180.381
	Peppermint .	180.381
	Spearmint	180.381
	Soybeans	180.381
PCNB	Tomatoes	180.319
Permethrin	Tomatoes	180.378
Propargite	Grapes	180.259
	Plums	180.259
Thiodicarb	Cottonseed .	180.407
	Soybeans	180.407
Triadimefon	Grapes	180.410
	Pineapple	180.410

# D. Pesticide Uses that Need a Section 409 FAR

EPA has determined that under its revised concentration policy the pesticide uses listed in this unit need section 409 FARs to prevent the adulteration of processed food.

In analyzing the need for section 409 FARs, EPA has taken into account not only existing section 408 tolerances but also available residue data bearing on whether the current section 408 tolerance should be revised under existing tolerance-setting policies. EPA has received large amounts of residue data as part of the reregistration program. Review of these data shows that, in several instances, the existing section 408 tolerance is set either too high or too low. Tolerance adjustments would normally be accomplished through the reregistration program.

EPA, however, sees no reason to wait until these tolerances are formally revised to determine whether the pesticide concentrates for the purpose of applying the coordination policy. EPA has decided that it should base its concentration decision upon the most recent data on residues in raw crops. If

those data indicate that section 408 tolerances should be adjusted, EPA has used the adjusted section 408 tolerance level as the basis for its determination of whether a section 409 FAR is needed. The basis for EPA's determination that the tolerance should be adjusted is in the docket.

In two cases (dicofol/plums and mancozeb/oats), the level of residues in the processed food is between the current section 408 tolerance and an adjusted lower 408 tolerance. If EPA were to make its determination of the need for a section 409 FAR based on the current higher tolerance, EPA might in this notice decide that revocation was not warranted only to have to revise that determination in the near future once the overall tolerance reassessment for the pesticide is complete. Once the overall tolerance reassessment for the pesticide is complete, EPA would take the identical action proposed here: EPA would explain why the tolerance needed to be lowered but then propose to revoke the existing tolerance because amending the existing tolerance would not be consistent with the coordination

In two other cases (dicofol/apples and propargite/apples), the level of residues in the processed food is higher than both the current and adjusted section 408 tolerances. In this case, adjusting the tolerance is irrelevant to the need for a section 409 FAR. Nonetheless, in all situations where a tolerance needs to be adjusted (whether raised or lowered), EPA believes the focus of the coordination policy analysis should be the tolerance value that would be set taking into account the most current

1. *Dicofol on apples.* The current section 408 tolerance for dicofol on apples is 5 ppm (40 CFR 180.163). Evaluation of new residue data indicates that the tolerance should be raised to 7 ppm.

This use needs a section 409 FAR for wet apple pomace. When apples are processed, residues may concentrate in both wet and dried apple pomace, with a greater potential concentration in dried apple pomace. A section 409 FAR for dried apple pomace would therefore cover the lower level of residues in wet apple pomace. In years past EPA often did not establish a separate section 409 FAR for wet apple pomace, which tended to obscure the fact that wet pomace itself was regarded by EPA as a significant animal feed. More recently, tolerance listings for apple pomace have included both wet and dried pomace, either with a single tolerance level based on the dried apple pomace or separate tolerance levels.

EPA determined in its June 1994 revision to the Residue Chemistry Guidelines Table II (June 8, 1994; 59 FR 29603) and reaffirmed in September 1995 (September 21, 1995; 60 FR 49150) that dried apple pomace is not a significant animal feed. FARs for dried apple pomace will eventually be revoked because they are not needed. However, without a FAR for dried pomace, wet apple pomace needs a FAR. Under the criteria of both the June 1994 and the September 1995 Table II, wet apple pomace is considered a significant animal feed. This is not a new determination by EPA; however, the decision to remove dried apple pomace highlighted the continued status of wet apple pomace as a significant animal feed. Wet apple pomace is also considered a RTE animal

Dicofol currently has no FARs for apple pomace, wet or dried. Under the new Residue Table II, no FAR is needed for dried apple pomace, but one is needed for wet apple pomace. The average concentration factor in the processing of wet apple pomace is 6.6 and the HAFT for dicofol on apples is 2.32. Because multiplying the average concentration factor by the HAFT exceeds the adjusted section 408 tolerance of 7 ppm for dicofol on apples, EPA believes that it is likely that some wet apple pomace will contain residues exceeding the adjusted tolerance level.

- 2. Dicofol on grapes. This use needs a section 409 for raisins. The average concentration factor in the processing of raisins is 6.6 and the HAFT for dicofol on grapes is 3.02. Because multiplying the average concentration factor by the HAFT exceeds the section 408 tolerance for dicofol on grapes (5 ppm), EPA believes that it is likely that some raisins will contain residues exceeding the tolerance.
- 3. *Dicofol on plums.* The current section 408 tolerance for dicofol on plums is 5 ppm (40 CFR 180.163). Evaluation of new residue data indicates that the tolerance should be reduced to 1 ppm. This use needs a section 409 FAR for prunes. The average concentration factor in the processing of prunes is 3.1 and the HAFT for dicofol on plums is 0.79. Because multiplying the average concentration factor by the HAFT exceeds the adjusted section 408 tolerance for dicofol on plums, EPA believes that it is likely that some prunes will contain residues exceeding the adjusted tolerance level.
- 4. *Mancozeb on oats.* The current section 408 tolerance for mancozeb on oat grain is 5 ppm (40 CFR 180.176). Evaluation of new residue data indicates that the tolerance should be reduced to

1 ppm. This use has a section 409 FAR for oat bran and oat flour. EPA believes that the bran FAR is needed under its concentration policy but the flour FAR is not. EPA considers oat bran a significant human food item which is RTE. The average concentration factor in the processing of oat bran is 2 and the HAFT for mancozeb on oats is 0.98 ppm. Because multiplying the average concentration factor by the HAFT exceeds the adjusted section 408 tolerance for mancozeb on oats, EPA believes that it is likely that some oat bran will contain residues exceeding the recommended tolerance level. After examining several processing studies involving mancozeb residues on grains, EPA has determined that the average concentration factor for the processing of flours is less than one.

In addition to a section 408 tolerance for oat grain, mancozeb has a section 408 tolerance for oat straw. EPA believes that straw production cannot be separated from grain production because oat grain and straw are harvested simultaneously from the mature plant. Oats would not be grown solely for straw considering its low value relative to grain. Therefore, it is not practical to limit use of a pesticide to oats grown for straw and the Agency is proposing to revoke the oat straw tolerance for mancozeb.

5. Mancozeb on wheat. The current section 408 tolerance for mancozeb on wheat grain is 5 ppm (40 CFR 180.176). Evaluation of new residue data indicates that the tolerance should be reduced to 1 ppm. This use has a section 409 FAR for wheat flour. EPA believes that the flour FAR is not needed under its concentration policy. After examining several processing studies involving mancozeb residues on grains, EPA has determined that the average concentration factor for the processing of flours is less than one. The section 409 FAR for wheat bran was revoked on July 14, 1993 (58 FR 37682) because it violated the Delaney clause. The bran FAR is needed to prevent the adulteration of wheat bran. Multiplying the average concentration factor in the processing of wheat bran (2) times the HAFT for mancozeb on wheat (0.97 ppm) yields a result exceeding the adjusted tolerance level (1 ppm).

In addition to a section 408 tolerance for wheat grain, mancozeb has a section 408 tolerance for wheat straw. Wheat production is similar to oat production with respect to straw, and EPA is therefore proposing to revoke the section 408 tolerance for mancozeb on wheat straw.

6. Propargite on apples. The current section 408 tolerance for propargite on

apples is 3 ppm (40 CFR 180.259). Evaluation of new residue data indicates that the tolerance should be raised to 20

This use currently has a section 409 FAR for dried apple pomace, which covers residues in wet apple pomace. The FAR for dried apple pomace is not needed; without the FAR for dried pomace, a FAR for wet apple pomace is needed. The average concentration factor in the processing of wet apple pomace is 5 and the HAFT for propargite on apples is 13.4 ppm. Because multiplying the average concentration factor by the HAFT exceeds the adjusted section 408 tolerance for propargite on apples, EPA believes that it is likely that some wet apple pomace will contain residues exceeding the tolerance.

7. Propargite on figs. This use has a section 409 FAR for dried figs and EPA believes that this FAR is needed under its concentration policy. The average concentration factor in the processing of dried figs is 2.7 and the HAFT for propargite on figs is 1.8 ppm. Because multiplying the average concentration factor by the HAFT exceeds the section 408 tolerance for propargite on figs (3 ppm), EPA believes that it is likely that some dried figs will contain residues exceeding the tolerance.

8. Simazine on sugarcane. This use has a corresponding section 409 FAR for molasses as human food and animal feed and previously was identified as needing FARs for syrup and bagasse. EPA considers molasses to be a RTE food and feed item. The average concentration factor in the processing of molasses is 10. A determination of the HAFT has not been made since the concentration factor is so large that the HAFT multiplied by that number is certain to appreciably exceed the section 408 tolerance (.25 ppm).

EPA expects that in most cases the HAFT will not be lower than the tolerance by a factor of two. This conclusion is based on EPA's experience with setting 408 tolerances (i.e., how they are derived based on the highest residue values) and with the relationships between average residues in field trials and either tolerances or maximum field trial residues, which are usually close to the tolerance. In most cases, average residues across all field trials for a given crop are 2 to 6 times less than a tolerance or maximum field trial value. The highest average field trial (HAFT) will be higher than the average residue across all trials. Therefore, in this particular case the Agency is confident that 10 times the HAFT will be appreciably higher than the 408 tolerance. Examples of the

relationships between average residues and tolerances or maximum field trial residues will be placed in the docket for this notice. EPA's conclusion regarding the level of simazine residues in sugarcane molasses is confirmed by a processing study in which sugarcane treated at the maximum application rate showed total residues of 0.63 ppm in molasses, well above the 0.25 ppm sugarcane tolerance. Therefore, EPA believes that it is likely that some molasses will contain residues exceeding the tolerance. Sugarcane syrup is not considered a significant human food and therefore no section 409 FAR is needed. Bagasse is not considered a significant animal feed.

9. Triadimefon on wheat. This use has a section 409 FAR for milled fractions of wheat. EPA considers milled fractions of wheat to be RTE human food (i.e. bran). The average concentration factor in the processing of milled fractions of wheat is 3.7 and the HAFT for triadimefon on wheat is 0.6 ppm. Because multiplying the average concentration factor by the HAFT exceeds the section 408 tolerance for triadimefon on wheat (1.0 ppm), EPA believes that it is likely that some milled fractions will contain residues exceeding the tolerance.

In addition to a section 408 tolerance for wheat grain, triadimefon also has section 408 tolerances for wheat green forage and straw. EPA is proposing to revoke the section 408 tolerance for triadimefon on wheat straw for the same reasons given for mancozeb. However, wheat forage in some areas is grown solely for the purpose of producing forage, and not grown to maturity to produce wheat grain. Some is grown in mixed stands with other grassy crops such as ryegrass, making it impractical to produce wheat grain from such fields. Based on these agronomic practices, EPA believes that a pesticide label restriction limiting the use of triadimefon to wheat grown for forage is practical. Therefore, EPA is not proposing to revoke the section 408 tolerance for triadimefon on wheat green forage even though the grain and straw tolerances are proposed for revocation.

V. Delaney Clause Determinations For Needed Section 409 FARs

#### A. Induce cancer

For each of the pesticides listed in Unit IV.D., section 409 FARs are either established or needed. In a number of published proposed revocations, EPA has previously determined that the five pesticides "induce cancer" within the meaning of the Delaney clause (59 FR

10993; 59 FR 33941; 60 FR 3607). Full copies of each of these reviews and other references in this document are available in the OPP Docket, the location of which is given under 'ADDRESSES" above. Information on dicofol is contained in OPP Docket OPP-300238, on mancozeb, propargite and simazine in OPP Docket OPP-300335, and on triadimefon in OPP Docket OPP-300360.

EPA is currently considering comments on the proposed revocations of section 409 FARs for propargite, mancozeb, simazine and triadimefon.

#### B. DES Proviso

EPA may establish or maintain a section 409 FAR for a pesticide that induces cancer if the DES proviso excepts the FAR from the Delaney clause. Thus, when a pesticide needing a FAR is found to induce cancer, EPA must determine if the FAR is nonetheless excepted from the Delaney clause prohibition by the DES proviso.

The *DES proviso* applies to a FAR when no detectable residues are expected in the animal commodities (meat, milk, poultry, eggs) as a result of animal consumption of feeds containing residues permitted by the FAR (60 FR 49142, September 21, 1995). If no detectable residues of the chemical can be found in the animal commodities, the FAR can be maintained or established.

The nine pesticide uses listed in Unit IV. D of this document have or need section 409 FARs that are or would be inconsistent with the Delaney clause. However, only three of these FARs are for animal feed items and thus have been further analyzed to determine whether they are allowed under the DES

1. Dicofol on wet apple pomace. EPA concludes that the DES proviso would not except the dicofol FAR from the Delaney clause. A dicofol FAR for wet apple pomace does not qualify because detectable residues in animal commodities are expected as a result of feeding treated wet apple pomace to animals. A memorandum explaining EPA's analysis is included in the docket.

- Propargite on wet apple pomace. EPA concludes that the DES proviso does not except the propargite FAR from the Delaney clause. The propargite FAR does not qualify because detectable residues in animal commodities are expected as a result of feeding propargite treated wet apple pomace to animals. A memorandum explaining EPA's analysis is included in the docket.
- 3. Simazine on molasses. EPA has previously concluded that the DES

proviso does not except the simazine FAR from the Delaney clause. (60 FR 49142, September 21, 1995).

### VI. Proposed Revocations

#### A. Section 408 Tolerances

EPA proposes that the nine section 408 tolerances listed in Table 3 of this unit be revoked. EPA no longer believes that these tolerances meet the statutory standard under section 408 ("protect the public health") because use of a pesticide under these tolerances is likely to result in residues in processed food exceeding such tolerance. Such residues will render the processed food adulterated under the FFDCA unless there is a section 409 FAR. Some of the nine section 408 tolerances have existing section 409 FARs that are inconsistent with the Delaney clause and they will be or have been revoked. The others need FARs but such FARs have not been, and under the Delaney clause cannot be, established.

As EPA explained in its recent statement on the coordination policy, (January 25, 1996, 61 FR 2378) it believes that, if the use of a pesticide under a section 408 tolerance is likely to result in residues in a processed food which Congress has, in the clearest terms, deemed unacceptable, Congress' heightened concern regarding such residues in processed food must be taken into account in determining whether the section 408 tolerance complies with the statutory standard for establishing or maintaining tolerances under section 408. Moreover, EPA believes that where evaluation of available data indicate that residues in processed food can exceed the section 408 tolerance, Congress' heightened concern about such residues is determinative of the finding under the section 408 standard, absent some extraordinary impact upon the food supply. EPA believes that its revised concentration policy (60 FR 31300, June 14, 1995) involves a reasonable approach to determining the likelihood of residues in processed food exceeding the associated section 408 tolerance. EPA expressly noted its willingness to use all relevant and appropriate data in examining this question. For example, EPA stated it would, where appropriate, consider some type of average residue value, average concentration values, and dilution factors for not RTE food.

Because EPA has concluded that the application of its concentration policy to each of the nine section 408 tolerances in the following Table 3 has shown that residues in processed food can exceed the section 408 tolerance and because removal of these uses is

unlikely to have a significant, much less extraordinary, impact on the food supply, EPA is proposing to revoke these section 408 tolerances because they fail to meet the section 408 standard for establishing or maintaining tolerances.

Table 3.—Section 408 Tolerances
Proposed for Revocation

Pesticide	Raw Crop	CFR Cite
Dicofol	Apples	180.163
	Grapes	180.163
	Plums	180.163
Mancozeb	Oats	180.176
	Wheat	180.176
Propargite	Apples	180.259
	Figs	180.259
Simazine	Sugarcane	180.213
Triadimefon	Wheat	180.410

### B. Impacts

As noted in Unit IV.D. of this document, evaluation of the nine pesticide uses listed in Table 3 of this document, under EPA's concentration policy yields the conclusion that, in all likelihood, residues in processed food can exceed the associated section 408 tolerance. For these pesticide uses, EPA also examined what the impact on the food supply would be if these uses were disallowed. EPA has concluded that removal of the uses would have little or no impact on the price or availability of food to the consumer. In fact, removal of most of these uses is not expected to have much effect on growers. For four of the uses no impact is expected. For the other five, the impact will be minor. Some individual apple, fig, and wheat growers may incur significant impacts. See Unit IX. A. below for details.

### VII. Consideration of Comments

Any interested person may submit comments on the proposed revocations of tolerance or EPA's decisions not to revoke certain tolerances on or before May 30, 1996 at the address given under the"ADDRESSES" section above. Before issuing final orders, EPA will consider all relevant comments. After consideration of comments, EPA will issue a final order. Such order will be subject to objections pursuant to section 409(f) (21 U.S.C. 348(f)). Failure to file an objection within the appointed period will constitute waiver of the right to raise issues resolved in the order in future proceedings.

#### VIII. Public Docket

A record has been established for this rulemaking under docket number [OPP-300415] (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, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can 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 all comments 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.

# IX. Regulatory Assessment Requirements

#### A. Executive Order 12866

EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 (58 FR 51735, October 4, 1993). Any comments or changes made during that review have been documented in the public record.

EPA has evaluated the economic impacts of this particular action for the nine proposed revocations. Below is a summary of the results of the economic analysis by crop.

Apples. The most significant economic impacts of the 408 tolerances currently proposed for revocation are expected on apples from the loss of propargite and dicofol. Eight states produce more than 70% of the apples grown in the United States; regionally, these include the Northwest (CA, OR and WA), Michigan in the Midwest, and the New York/Pennsylvania and North/South Carolina areas of the East.

In these areas, losses will be more acute for propargite which is used on 29% of the overall acreage, but up to 50% of the acreage in New York and Michigan. Dicofol, on the other hand, averages use on only 5% of the overall acreage, with a range of 3% - 9% in the major producing states.

The most likely chemical alternatives are projected to be fenbutatin-oxide, formetanate hydrochloride, and oxythioquinox. These alternatives are more toxic than propargite and dicofol to some beneficial insects in some states, but would likely be used as replacements in most cases. There are mixed results on efficacy of the alternatives compared to propargite and dicofol for controlling mite pests from field trials. Many trials suggest the alternatives have equal or superior efficacy, while some others suggest that propargite and dicofol are superior. The Agency assumed a three percent yield loss due to substitution of the alternatives, resulting in a projected loss of nearly \$16 million annually to current users of propargite and dicofol. This may overstate potential yield loss because the data on the relative efficacy of these pesticides are mixed. This figure does not include losses from higher toxicity of alternatives to beneficial insects, or increased development of resistance to the remaining alternatives. Alternatives are approximately the same or lower cost than propargite and dicofol, so that there would be little increased cost for

Figs. Since there are no miticide alternatives to propargite, annual loss to growers could be up to \$100,000 in those years when mite pressures are high

alternatives.

Wheat. Triadimefon use on wheat is insignificant. Mancozeb is used on less than 5% of the wheat acres, and numerous alternatives, some of which may be more efficacious than mancozeb, are available.

Grapes. Impacts will be limited to the loss of dicofol, which is expected to cause only marginal impacts. Dicofol was not used in California in 1994, and is not recommended by grape specialists because its non-selective mode of action kills beneficial insects. The preferred alternative (propargite) offers superior mite control while not harming beneficial insects.

The Delaney clause prohibits establishing or maintaining section 409 FARs for any pesticide meeting the "induces cancer" standard, without regard to economic impacts. However, this proposed action to revoke section 408 tolerances is due to the combined effect of the Delaney clause and EPA's

coordination policy. EPA believes that the impacts due to these proposed revocations (and ultimately the cancellation of the registered uses) are less burdensome than the alternative of maintaining these tolerances and registrations. If the uses and 408 tolerances remain in effect without needed 409 FARs (prohibited by the Delaney clause), lawfully treated foods could potentially be adulterated, and subject to seizure, and the need for costly Federal monitoring and enforcement would increase. The possibility of adulterated foods could create uncertainty among pesticide users and food processors and erode consumer confidence in the food supply.

#### B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354; 94 Stat. 1164, 5 U.S.C. 601 et seq.) requires EPA to analyze regulatory options to assess the economic impact on small businesses, small governments, and small organizations.

Regulating pesticide residues in food is, by its nature, indiscriminate with respect to the size of the business or farm that was the source of the food. The existence or absence of a tolerance, and the levels at which they are set must logically apply to all food available to U.S. consumers. It is also not feasible to segregate and track food from different farm sizes, once it is in channels of trade. Therefore, there is no potential regulatory option that would treat small farms differently from large farms with respect to pesticide

The Delaney clause leaves no option to retain the applicable section 409 FARs. The section 408 tolerances could either be revoked, as called for by the coordination policy, or maintained in the absence of the needed 409 FARs. It is not feasible to quantify the economic impacts of retaining the 408 tolerances, for the reasons discussed above, and therefore a comparison of the impacts of these two options cannot be made. The Agency's choice to revoke the 408 tolerances will not disproportionately affect small farms over large farms, since the loss of a pesticide is generally proportional to the crop acreage.

#### C. Unfunded Mandates Reform Act and Executive Order 12875

Under Title II of the Unfunded Mandates Reform Act of 1995 (Pub.L. 104–4), this action does not result in the expenditure of \$100 million or more by any State, local or tribal governments, or by anyone in the private sector, and will not result in any "unfunded mandates"

as defined by Title II. The costs associated with this action are described in Unit IX. A of this notice.

Under Executive Order 12875 (58 FR 58093, October 28, 1993), EPA must consult with representatives of affected State, local, and tribal governments before promulgating a discretionary regulation containing an unfunded mandate. This action does not contain any mandates on States, localities or tribes and is therefore not subject to the requirements of Executive Order 12875.

#### D. Paperwork Reduction Act

This order does not contain any information collection requirements and therefore is not subject to the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 180

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

Dated: February 26, 1996.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR, chapter I, part 180 be 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.

## §180.163 [Amended]

2. In § 180.163, in the paragraph beginning with "5 parts per million...," remove the entries "apples," "grapes," and "plums (fresh prunes),".

## §180.176 [Amended]

3. In § 180.176 by revising the paragraphs beginning with "25 parts per million..." and "5 parts per million..." to read respectively as follows:

# §180.176 Coordination product of zinc ion and maneb; tolerances for residues.

25 parts per million in or on the straws of barley and rye.

5 parts per million in or on celery; corn fodder and forage; and the grains of barley and rye.

## §180.213 [Amended]

4. By removing from the table in § 180.213 the entry for "sugarcane".

### §180.259 [Amended]

5. By removing from the table in § 180.259 the entries for "apples" and "figs".

## §180.410 [Amended]

6. By removing from the table in  $\S$  180.410 the entries for "Wheat, grain", and "Wheat, straw".

[FR Doc. 96–4836 Filed 2–29–96; 8:45 am] BILLING CODE 6560–50–F