ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300360B; FRL–5388–2]

RIN 2070–AB78

Revocation of Pesticide Food Additive Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking six food additive regulations (tolerances) for four pesticides. EPA is revoking four tolerances because they violate the Delaney clause of the Federal Food, Drug, and Cosmetic Act, and the other two tolerances because they are not needed to prevent adulterated food.

EFFECTIVE DATE: This final rule is effective September 27, 1996. Written objections, requests for a hearing, and/or requests for stays identified by the docket number OPP–300360B, must be submitted by August 28, 1996.

ADDRESSES Written objections and hearing requests, identified by the docket number, [OPP–300360B], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300360B]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

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 in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT By mail: Jean M. Frane, Policy and Special Projects Staff (7501C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1113, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–5944. e-mail: frane.jean@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This document is divided into the following areas for discussion: Table of Contents

I. Introduction
A. Regulated Entities
B. Terms and Acronyms
C. Statutory Background
D. Regulatory Background
E. EPA Actions Since Proposed Rule
F. Today's Action
II. Relevant Policy Changes Since the Proposal
A. Concentration Policy
B. Ready-to-Eat Definition
C. RAC Interpretation
III. Decision Framework
IV. Is a Processed Food Tolerance Needed?
A. Acephate in Food Handling Establishment
B. Imazalil in Citrus Oil
C. Iprodione on Dried Ginseng
D. Iprodione on Raisins
E. Triadimefon on Milled Fractions of Wheat (Wheat Bran)
F. Triadimefon on Milled Fractions of Barley (Barley Bran)
V. Do Needed Processed Food Tolerances Violate the Delaney Clause?
VI. Revocations
A. Processed Food Tolerances That are Not Needed
B. Processed Food Tolerances That Violate the Delaney Clause
VII. General Comments Common to All Proposed Revocations.
VIII. Comments Related to Specific Pesticides
A. Acephate
B. Triadimefon
C. Iprodione
IX. Procedural Matters
A. Filing of Objections and Requests for Hearings
B. Effective Date
C. Request for Stays of Effective Date
X. Regulatory Assessment Requirements
A. Executive Order 12866
B. Regulatory Flexibility Act
C. Paperwork Reduction Act
D. Unfunded Mandates Reform Act and Executive Order 12875
E. Review by Congress and the General Accounting Office

I. Introduction

A. Regulated Entities

Category	Examples of Regulated Entities
Industry	Users of the pesticides covered by this notice
.....	Food processors

This table is not exhaustive, but is a guide to the entities EPA believes are regulated by this action.

B. Terms and Acronyms

In today's document, EPA uses a number of terms and acronyms that may not be familiar to the reader. For the convenience of readers, principal terms and acronyms used in this document are listed here.

Federal Food, Drug, and Cosmetic Act - FFDCA

Federal Insecticide, Fungicide and Rodenticide Act - FIFRA

408 tolerance - a raw food tolerance established under section 408 of the FFDCA.

409 tolerance - a processed food tolerance established under section 409 of the FFDCA.

CF - concentration factor

DF - dilution factor

HAFT - highest average field trial

RAC - raw agricultural commodity

RTE - ready to eat

C. Statutory Background

The Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., authorizes the establishment by regulation of maximum permissible levels of pesticides in foods. Such regulations are commonly referred to as ''tolerances.'' Without such a tolerance or an exemption from the requirement of 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. 331, 342. Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture. EPA can establish a tolerance in response to a petition or on its own initiative.

The FFDCA has separate provisions for tolerances for pesticide residues in raw agricultural commodities (RACs) and in processed food. EPA establishes tolerances, or exemptions from tolerances when appropriate, for RACs under section 408 (hereafter referred to as ''408 tolerances'' or ''RAC tolerances''). 21 U.S.C. 346a. EPA establishes food additive regulations for pesticide residues in processed foods under section 409, which pertains to ''food additives.'' 21 U.S.C. 348. Food additive regulations under section 409 are referred to hereafter as ''409 tolerances'' or ''processed food tolerances.''

Section 409 tolerances are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, a pesticide residue in processed food generally will not render the food adulterated if the residue results from application of the pesticide to a RAC and the residue in the processed food when ready to eat is below the RAC tolerance. This exemption in section 402(a)(2) is commonly referred to as the ''flow-through'' provision because it allows the RAC tolerance to flow through and apply to the processed food forms as well. Thus, a 409 tolerance is only necessary to prevent foods from being deemed adulterated when the level of the pesticide residue in a processed food when ready to eat is greater than the tolerance established for the RAC, or if the processed food itself is treated or comes in contact with a pesticide.

If a 409 tolerance 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)). Relevant factors in this safety determination include (1) the probable consumption of the pesticide or its metabolites; (2) the cumulative effect of the pesticide in the diet of man or animals, taking into account any related substances in the diet; and (3) appropriate safety factors to relate the animal data to the human risk evaluation. Section 409 also contains the Delaney clause, which specifically provides that ''no additive shall be deemed to be safe if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.''

D. Regulatory Background

1. On January 18, 1995 (60 FR 3602)(FRL–4910–8), EPA published in the Federal Register a proposal to revoke six 409 tolerances for 4 pesticides. EPA's action was prompted by a decision of the Ninth Circuit Court of Appeals, which ruled on July 8, 1992, in the case of *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 409 tolerance for a pesticide which ''induces cancer,'' no matter how infinitesimal the risk.

In response to the court's decision in *Les v. Reilly*, EPA identified and proposed to revoke all 409 tolerances for pesticides which it determined ''induce cancer in man or animals.'' EPA decided to evaluate these pesticides in phases. The initial phase of revocations included 26 uses of 7 pesticides and was finalized on March 22, 1996 (61 FR 11993)(FRL–5357–7). The second phase of revocations includes 6 uses of 4 pesticides and was proposed on January 18, 1995 (60 FR 3602). Today's final revocations address those pesticides. A third set of revocations was proposed on September 21, 1995 (60 FR 49141)(FRL–4977–3) and will be finalized by March 1997.

E. EPA Actions Since Proposed Rule

1. *Settlement of California v. Browner case.* 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 a timetable for making the decisions. Today's revocations comply with the timeframes in that settlement.

2. *Revised tolerance-setting policies.* In September 1993 the National Food Processors' Association (NFPA) filed a petition with the EPA, challenging a number of policies under which EPA administers its tolerance-setting program, including the concentration policy, ready-to-eat policy and coordination policy. Several of these policies are relevant to today's revocation decisions. In the Federal Register of June 14, 1995 (60 FR 31300)(FRL–4944–2) and January 25, 1996 (61 FR 2378)(FRL–4991–9), EPA responded to the NFPA petition by modifying or establishing policies concerning concentration of residues, ready-to-eat foods, raw agricultural commodities and coordination of its regulatory authorities. Unit II of this document summarizes the policy changes that are relevant to today's revocations.

F. Today's Action

EPA is revoking the 409 tolerances for six uses of four pesticides. Table 1 below summarizes the revocations and their basis. Each of these is discussed later in this notice.

Pesticide	CFR Citation	Commodity	Basis for Revocation
Acephate	185.100	Food handling establishments	Violates Delaney
Imazalil	185.3650	Citrus oil	Not needed
Iprodione	185.3750	Dried Ginseng	Violates Delaney
Iprodione	Do.	Raisins	Violates Delaney
Triadimefon	185.800	Barley, milled fractions (except flour)	Not needed
	Do.	Wheat, milled fractions (except flour)	Violates Delaney

The 409 tolerance revocations being finalized in this notice were proposed on January 18, 1995, before EPA had responded to the NFPA petition and adopted its new policies. In addition, EPA received petitions from registrants of three pesticides requesting revocation of four 409 tolerances (imazalil/citrus oil, iprodione/raisins and dried ginseng, and triadimefon/barley milled fractions) on the basis that they are not needed. For each petition, EPA published a notice of availability in the Federal Register requesting comment. Although not required to do so, where appropriate EPA has based its revocation decision on the reasons cited by the petitioners rather than the requirements of the Delaney clause as proposed.

II. Relevant Policy Changes Since the Proposal

A. Concentration Policy

In its June 1995 notice, EPA announced a new policy on how it would determine whether a pesticide needs a 409 tolerance. To determine whether the use of a pesticide on a growing crop needs a 409 tolerance in addition to a 408 tolerance, EPA evaluates the likelihood that the residue levels in the processed food when ready to eat will exceed the 408 tolerance level. In the past, EPA focussed almost exclusively on the results of processing studies using treated crops in making this determination. EPA now considers a greater range of information in determining the likelihood that residues in processed food will exceed the 408 tolerance. For example:

1. Mixing and blending of treated food commodities decreases the likelihood that residues in processed food will exceed the 408 tolerance. EPA takes potential mixing and blending into account by using information on the highest average field trial residue (referred to as the HAFT).

2. If multiple processing studies demonstrate different concentration factors (CFs), EPA now uses the average CF rather than the highest CF to determine the expected level of concentration.

3. At the same time, EPA examines processing studies to ensure that they reflect typical commercial practices. If a study does not include a step (e.g., washing) that is considered typical practice in processing a RAC, EPA may decide not to include that study in the calculation of the average CF. EPA's concentration policy bears on today's decision on triadimefon/wheat.

B. Ready-to-Eat Definition

In its June 1995 notice, EPA also adopted a definition of ''ready to eat'' (RTE) as it applies to human food and animal feed. EPA stated it would interpret the phrase ''RTE food'' as meaning food ready for consumption ''as is'' without further preparation. If a food is not RTE, EPA considers the degree of dilution that occurs in producing a RTE food from the not-RTE food in determining the likelihood that residues in RTE food will exceed the 408 tolerance. EPA's RTE definition bears on today's decision on imazalil on citrus oil.

C. RAC Interpretation

On January 25, 1996 (61 FR 2386), EPA published its interpretation of the term RAC as applied to dried commodities under the FFDCA. EPA based its interpretation on the purpose of drying, such that commodities dried for the purpose of creating a new marketable commodity are treated as processed food, while those dried for storage or transportation needs are treated as raw foods. EPA's RAC interpretation bears on today's decision on iprodione on raisins.

III. Decision Framework

In analyzing whether the six 409 tolerances addressed in this document should be revoked, EPA generally has used the following decision framework. First, EPA determined whether a 409 tolerance was necessary to prevent adulteration, applying its RAC, concentration, and RTE policies. Unit IV.A. of this document discusses EPA's determination for each chemical. If no 409 tolerance is needed, EPA in most cases has revoked the 409 tolerance on that ground. If a 409 tolerance is needed, then EPA has determined whether that 409 tolerance is permitted under the Delaney clause. Unit IV.B. of this document discusses the Agency's determinations on ''induce cancer'' for each chemical for which a 409 tolerance is needed. EPA does not believe that this decision hierarchy is legally required under the FFDCA but has chosen this approach in its discretion.

Under current policy, a 409 tolerance is needed when EPA determines that some processed food can contain residues exceeding the section 408 tolerance. This determination is made on a case-by-case basis, taking into account the sensitivity of the analytical method used to detect the residues.

Before determining whether a 409 tolerance is needed, however, EPA also examines whether available residue data indicate that the current 408 tolerance should be revised. EPA has received large amounts of residue data as part of the pesticide reregistration program of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Review of these data shows that, in one instance (triadimefon/wheat), the existing 408 tolerance should be lowered.

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 a 408 tolerance should be adjusted, EPA has used the adjusted 408 tolerance level as the basis for its determination whether a 409 tolerance is needed because the pesticide concentrates. The basis for EPA's determination that a 408 tolerance should be adjusted is in the docket.

In examining whether a 409 tolerance is needed, EPA followed a stepwise process involving a series of questions. In brief, the questions are:

1. Is there actual concentration of residues during processing? If processing studies demonstrate that the level of residues in the processed food is less than or equal to the level of residues in the precursor crop (i.e., no ''concentration in fact''), residues in the processed food would not be expected to exceed the 408 tolerance and no 409 tolerance is needed.

2. If there is actual concentration, what is the concentration factor? If there are multiple processing studies, what is the average CF? Does the use of an average CF in itself alter EPA's determination of the likelihood of residues in processed food exceeding the RAC tolerance?

3. Is the commodity mixed or blended during processing, such that use of the HAFT value is appropriate?

4. Can the pesticide residue in the processed food exceed the section 408 tolerance, taking into account the HAFT and CF (or average CF if appropriate).

5. Is the processed food form a not RTE food? If the processed food is not RTE, a 409 tolerance is not needed for that food. If residues in a processed not RTE food can exceed the 408 tolerance, EPA will establish a maximum residue level under FFDCA section 701.

6. What is the likelihood that residues in RTE food can exceed the 408 tolerance? If the dilution of residues in RTE food preparation is greater than the concentration of residues in processing (DF > CF), it is likely that the residues in the RTE food will be less than the 408 tolerance. In this case, no 409 tolerance would be necessary for the RTE food. If, as is frequently the case, there is more than one RTE food form, EPA must determine whether residues in the food form having the highest level of expected residues (the lowest dilution factor) can exceed the 408 tolerance.

If, after consideration of the above factors, EPA determined that a 409 tolerance is needed, EPA then examines whether the existing 409 tolerance violates the Delaney clause.

IV. Is a Processed Food Tolerance Needed?

EPA has determined that under its revised concentration, RTE, and RAC policies, three 409 tolerances are not needed to prevent adulterated food, while three 409 tolerances are needed. This unit discusses the Agency's findings with respect to each pesticide and use.

A. Acephate in Food Handling Establishments

The current 409 tolerance for the use of acephate in food handling establishments is 0.02 ppm. Acephate is directly applied in food handling establishments and residues in processed food are likely to result from application. Policies on RAC, concentration, and dilution in RTE foods are not relevant to processed foods where residues result from direct application rather than carryover from raw foods. Therefore, a 409 tolerance is needed to prevent adulterated food.

B. Imazalil in Citrus Oil

The current 408 tolerance for residues of imazalil in citrus is 10 ppm (40 CFR 180.413) and the 409 tolerance is 25 ppm (40 CFR 185.3650). On December 14, 1995, EPA published notice in the Federal Register (60 FR 64163)(FRL–4986–5) of a petition filed by Janssen Pharmaceutica which sought to revoke the 409 tolerance because it is not needed. Janssen maintained that citrus oil is not a RTE food, and submitted data showing the maximum residue of imazalil in RTE foods to be below the 408 tolerance.

EPA has reviewed the public comments and reconsidered the available processing studies in light of its RTE policy. EPA agrees with Janssen that citrus oil is not consumed ''as is,'' and is therefore not a processed RTE food. Typically citrus oil is incorporated into food such as candies as a flavoring agent. The minimum level of dilution of citrus oil in RTE foods (its use in chewing gum) is 238X, and residues in the RTE food items are not expected to exceed the 408 tolerance of 10 ppm. Therefore a 409 tolerance is not needed.

C. Iprodione on Dried Ginseng

The current 408 tolerance for ginseng is 2 ppm (40 CFR 180.399) and the 409 tolerance for iprodione on dried ginseng is 4 ppm (40 CFR 185.3750). On June 5, 1996, EPA published notice in the Federal Register (61 FR 28578)(FRL–5374–8) of a petition filed by Rhone-Poulenc which sought to revoke the 409 tolerance because it is not needed. Rhone-Poulenc claims that dried ginseng is not a RTE commodity, and once diluted to its RTE form, the residues do not exceed the 408 tolerance. No comments were received on the petition.

EPA has concluded that the petition is moot. In response to comments received on EPA's proposed revocation, EPA has determined that dried ginseng meets the criteria for a RAC. Ginseng is dried not to create a new marketable commodity, but as an essential step in preventing rotting during storage and transportation. EPA's determination that ginseng is a RAC means that EPA need not further evaluate Rhone- Poulenc's petition.

However, EPA has not had time since its reclassification of dried ginseng to provide notice and comment of the RAC classification as a possible alternate ground for revocation. EPA is obligated under the terms of its consent order in the *California v. Browner* case to issue a final decision on iprodione on dried ginseng by July 18. The basis for its original proposal has not changed: the current 409 tolerance for dried ginseng violates the Delaney clause because iprodione induces cancer within the meaning of the Delaney clause. EPA does not believe it should simply announce its RAC determination in this final notice without providing notice and comment. In its discretion, therefore, EPA is revoking the current 409 tolerance for iprodione on ginseng on Delaney grounds as proposed.

D. Iprodione on Raisins

The current 408 tolerance for iprodione on grapes is 60 ppm (40 CFR 180.399) and the 409 tolerance for raisins is 300 ppm (40 CFR 185.3750). In the same petition noted above for iprodione/ginseng, Rhone-Poulenc sought to have EPA revoke the 409 tolerance for raisins because it is not needed.

Rhone-Poulenc argues that the likelihood of iprodione residues in raisins from application to grapes is minimal because iprodione use can be limited to grapes grown for fresh table use by means of a label statement (''Grapes treated with [iprodione] must not be used to produce raisins''). The label statement, Rhone-Poulenc states, will be enforceable for two reasons: First, because grapes intended for fresh use versus raisin use have sufficiently different cultural practices that a label limitation based upon ''market segregation'' is practical, and second, because Rhone-Poulenc will undertake an educational program to ensure that grape growers, pesticide applicators, State regulators and raisin producers will be fully informed of the proposed label prohibition against use of iprodione on grapes intended for raisins. Rhone-Poulenc also asserts that current tracking systems for pesticide use in California would provide adequate oversight over the use of iprodione on grapes, and that contractual arrangements with raisin producers also would preclude use on grapes intended for raisins.

With respect to the feasibility and effectiveness of ''market segregation'' based on cultural practices, Rhone-Poulenc suggested that differences in trellising systems, in pesticides used (use of the plant hormone gibberellin for fresh grapes) and in irrigation practices would ensure market segregation. However, Rhone-Poulenc provided no support for these assertions, such as substantiating information from the State, grape growers, or raisin producers.

Based on other information available to EPA, it appears that the cultural practices cited in the petition do occur. However, based on that information, EPA has concluded that the level of market segregation between grapes grown for the fresh/wine/juice market and grapes grown for the raisin market is insufficient to support a finding that a 409 tolerance would not be necessary to protect the public health.

The National Academy of Sciences, in their Report on ''Pesticides in the Diets of Infants and Children'' (1993), states that children may be a sensitive subpopulation; children differ significantly from adults in their body systems and potential physiological and biological responses to pesticide exposures. Information from the USDA National Food Consumption Survey (1977–78) indicates that children age 1 to 6 consume more than 4 times the amount of raisins on a body weight basis than the U.S. population at large. Because of this disproportionate consumption, and the different sensitivities of children to pesticides in their diet, EPA, as a policy matter, has concluded that it must have a high degree of confidence that grapes treated with iprodione will not be diverted to raisin production. The information currently available to the Agency suggests that complete market segregation between grape and raisin production cannot be achieved, and that Rhone-Poulenc's proposed labeling restrictions and education program will not prevent iprodione residues on raisins.

The Thompson seedless grape is by far the major grape grown for both fresh table grapes and for raisin production. In addition, while varietal wine grapes are not used to make raisins, a small percentage of Thompson seedless grapes that are grown for the wine/juice market may be made into raisins. Thus there is a significant potential for crossover or diversion of grapes intended for fresh or wine/juice use into raisin processing. While there are no data directly addressing the amount of crossover between grape markets, information from experts and extrapolated from the

California Agricultural Statistics Service (contained in the docket) indicates that a low but relatively constant amount of grapes grown for fresh use and wine/juice use are diverted into raisin production. The following Table 2 sets out potential grape diversion to raisin production.

TABLE 2.— DIVERSION OF GRAPES TO RAISIN PRODUCTION

Diversion from grapes intended for:	Percentage of grapes diverted	Maximum Percentage of Raisin Production
Fresh market use.	1 to 4 percent	1.8 percent
Wine/juice use.	1 to 5 percent	1.9 percent
Total		**3.7 percent**

Thus, market segregation based on the cultural practices cited by Rhone-Poulenc, while substantial, clearly does not account for or prevent some diversion of grapes to raisins.

EPA's concern about the lack of complete market segregation is heightened by the fact that grapes for fresh use are likely to be treated with iprodione more frequently and later in the growing season than grapes intended for raisins. If diversion occurs late in the grape season, residues in raisins produced from diverted fresh market grapes could be significantly higher than in raisins from grapes grown for raisin production. In years with heavy early rainfall, when natural drying is not possible, fresh market grapes may be diverted into golden raisin production (oven-dried) after iprodione application. The potentially higher risk posed by raisins diverted from fresh/wine/juice grape production reinforces EPA's belief that complete market segregation is essential.

In its policy statement of June 14, 1995 (61 FR 31300), EPA discussed the possibility that market segregation could be used to determine that a 409 tolerance would not be needed. EPA said that it believed that total market segregation would be difficult to achieve. The information available to EPA on grapes/raisins illustrates this difficulty. Without a clear demonstration that market segregation can be achieved and monitored, EPA cannot conclude that a labeling prohibition premised on market segregation would be an effective means of ensuring that iprodione treated grapes are not used for raisins.

Rhone-Poulenc contends that contractual arrangements govern the purchase of grapes for raisins and that limitations on iprodione use on such grapes can therefore be enforced by raisin processors. Even if true, and the petition provided no information to support this assertion, contracts for raisin production would not affect the production of, or pesticides used on, grapes grown for other uses. Contracts between raisin processors and growers obligate the grower to sell his grapes to a particular buyer, but may not necessarily be brought to bear on a grower of fresh market grapes who sells his crop to a non-contracted raisin processor.

In its June 1995 policy statement, EPA discussed the possibility that processing industry practices could be taken into account in determining the likelihood of residues in processed food. One of the criteria that EPA would need to consider is whether residue levels in the raw food (grapes) could be adequately monitored by the processing industry such that EPA could be assured that there is no reasonable expectation of residues in raisins. EPA has no information on the residue monitoring practices of the raisin industry, and therefore cannot evaluate whether grapes bearing iprodione residues could be adequately detected.

For the same reasons, Rhone-Poulenc's proposed education/information and labeling proposals, and existing systems for tracking, authorizing and reporting pesticide use do not alleviate EPA's concerns. All of these activities focus on ensuring that iprodione is not used on grapes initially intended for raisins, but do not address the possibility that grapes grown for fresh or wine/juice use (which may also be Thompson seedless variety) may be diverted. By the time a decision is made to divert grapes into raisin processing, iprodione may have already been applied several times. Systems for tracking pesticide use do not prevent a grower from selling grapes unusable for the fresh market to a raisin processor directly. Other grapes may be sold to an intermediary, who purchases cull grapes or ''strippings'' and funnels the grapes into whichever processing stream offers the greatest return (wine/juice or raisins). In this latter case, the grape grower may not know the destination of his grapes, and the intermediary may not know whether iprodione has been applied to the grapes.

In sum, EPA believes that complete market segregation is needed, and is not persuaded on the basis of the available information that market segregation of grapes can be achieved. EPA therefore denies the Rhone-Poulenc petition with respect to raisins. Because raisins are a processed RTE food under EPA's interpretation, a 409 tolerance is needed.

E. Triadimefon on Milled Fractions of Wheat (Wheat Bran)

The current 408 tolerance for triadimefon on wheat grain is 1 ppm (40 CFR 180.410) and the 409 tolerance for milled fractions of wheat, except flour, is 4.0 ppm (40 CFR 185.800). Evaluation of new residue data indicates that the 408 tolerance should be reduced to 0.2 ppm. Based on the HAFT of 0.14 ppm for the wheat grain and an average CF of 3.7 in wheat bran, the expected residue in wheat bran is calculated as 0.52 ppm. (The HAFT multiplied by the CF is 0.14 ppm $\times$ 3.7 = 0.52 ppm.) Therefore, EPA believes that it is likely that some wheat bran will contain residues exceeding an adjusted RAC tolerance at 0.2 ppm. Milled fraction wheat bran is a processed RTE food and needs a 409 tolerance.

F. Triadimefon on Milled Fractions of Barley (Barley Bran)

The current 408 tolerance for triadimefon on barley grain is 1 ppm (40 CFR 180.410) and the 409 tolerance for milled fractions of barley (except flour) is 4.0 ppm (40 CFR 185.800). This use is no longer registered and the 409 tolerance is no longer needed. On June 19, 1996, EPA published a notice (61 FR 31081)(FRL–5379–7) proposing to revoke the 408 tolerance for triadimefon on barley grain, forage and straw and the 409 tolerance on milled fractions of barley because they are not needed.

In its notice of June 19, 1996, EPA proposed to make the triadimefon revocations effective as of May 23, 1997. However, the registration was cancelled in August 1993, effective November 1993, with provision for sale and distribution of existing stocks of triadimefon labeled for use on barley until May 1995. More than a year has passed since the last product bearing the barley use could be sold and distributed. EPA now believes that this year is sufficient time for barley treated with triadimefon to have cleared channels of trade. Since no comments were received indicating that triadimefon is still being used on barley, EPA is revoking the various barley tolerances on the same day as the other revocations in this notice (effective 60 days after publication in the Federal Register). EPA believes that since the cancellations were at the request of the registrant in August 1993, it is unlikely that significant amounts of triadimefon were being used on barley even then. Therefore, this earlier revocation should not result in economic impacts from loss of use or adulterated barley.

V. Do Needed Processed Food Tolerances Violate the Delaney Clause?

EPA has determined that 409 tolerances are needed for acephate/food handling establishments, iprodione/raisins and triadimefon/wheat bran. And although EPA has determined that a 409 tolerance is not needed for iprodione/dried ginseng because dried ginseng is a RAC as explained in Unit IV.C. of this document, EPA has chosen not to revoke the current 409 tolerance on that ground.

If a 409 tolerance is needed to prevent adulterated food, EPA must determine whether the tolerance is permitted under the Delaney clause, i.e., whether the pesticide induces cancer within the meaning of the Delaney clause. In its January 18 proposal, EPA proposed to determine that acephate, iprodione, imazalil and triadimefon ''induce cancer'' within the meaning of the Delaney clause. Copies of EPA's reviews of each chemical and other references in this document are available in OPP docket 300360.

In construing the ''induce cancer'' standard as to animals, EPA follows a weight-of-the-evidence approach. In regard to animal carcinogenicity, EPA, in general, interprets ''induces cancer'' to mean:

> The carcinogenicity of a substance in animals is established when administration in an adequately designed and conducted study or studies results in an increase in the incidence of one or more types of malignant (or, where appropriate, benign or a combination of benign and malignant) neoplasms in treated animals compared to untreated animals maintained under identical conditions except for exposure to the test compound. Determination that the incidence of neoplasms increases as the result of exposure to the test compound requires a full biological, pathological, and statistical evaluation. Statistics assist in evaluating the biological significance of the observed responses, but a conclusion on carcinogenicity is not determined on the basis of statistics alone. Under this approach, a substance may be found to ''induce cancer'' in animals despite the fact that increased tumor incidence occurs only at high doses, or that only benign tumors occur, and despite negative results in other animal feeding studies. (See 58 FR 37863, July 14, 1993, 53 FR 41108, October 19, 1988, and 52 FR 49577, December 31, 1987.)

EPA has considered the comments submitted on the proposed rule, and has applied this interpretation to the 3 pesticides that need 409 tolerances.

Based on this analysis, EPA concludes that acephate, iprodione, and triadimefon induce cancer within the meaning of the Delaney clause. Because EPA has determined that the 409 tolerance for imazalil in citrus oil should be revoked on grounds other than the Delaney clause, the Agency is not issuing a final finding that imazalil induces cancer within the meaning of the Delaney clause.

VI. Revocations

A. Processed Food Tolerances That Are Not Needed

Imazalil/citrus oil. EPA is revoking the 409 tolerance for imazalil in citrus oil (40 CFR 185.3650). EPA is revoking this tolerance because the Agency has determined that it is not needed to prevent adulterated food. As discussed in Unit IV.B. of this document, EPA is revoking this 409 tolerance because citrus oil is not a processed RTE food, and residues in RTE foods are not likely to exceed the 408 tolerance for citrus.

Triadimefon/milled fractions of barley. EPA is revoking the 409 tolerance for triadimefon in or on milled fractions of barley (except flour) (40 CFR 185.800). As discussed in Unit IV.F. of this document, EPA is revoking this tolerance because the use is no longer registered. For the same reason, EPA is revoking the 408 tolerances for triadimefon on barley grain, straw and green forage.

B. Processed Food Tolerances That Violate the Delaney Clause

Acephate/food handling establishments. EPA is revoking the 409 tolerance for acephate in food-handling establishments (40 CFR 185.100). EPA is revoking this tolerance because the Agency has determined that acephate induces cancer in animals. Thus, the 409 tolerance violates the Delaney clause.

Iprodione/dried ginseng. EPA is revoking the 409 tolerance for iprodione in dried ginseng (40 CFR 185.3750). As discussed in Unit IV.C of this document, although EPA has determined that dried ginseng is a RAC, EPA has chosen to revoke the 409 tolerance because iprodione induces cancer in animals. Thus the 409 tolerance violates the Delaney clause.

Iprodione/raisins. EPA is revoking the 409 tolerance for iprodione in raisins (40 CFR 185.3750). EPA is revoking this tolerance because the Agency has determined that iprodione induces cancer in animals. Thus, the 409 tolerance violates the Delaney clause.

Triadimefon/milled fractions of wheat. EPA is revoking the 409 tolerance for triadimefon in or on milled fractions of wheat (except flour)(40 CFR 185.800). EPA is revoking this tolerance because the Agency has determined that triadimefon induces cancer in animals. Thus, the 409 tolerance violates the Delaney clause.

VII. General Comments Common to All Proposed Revocations

Because EPA's proposed revocation of these 409 tolerances was published prior to EPA's issuance of its modified tolerance-setting policies, a number of comments were received urging EPA to reconsider many of those tolerance setting policies, including the coordination, concentration, RTE and RAC policies. EPA has now adopted these policies. EPA presumes that the comments pertaining to the concentration, RTE, RAC and coordination policies were based on EPA's previous policies, and not to its revised policies. Because these comments were all previously raised in response to the petition submitted by the National Food Processors' Association, EPA believes that it has adequately addressed the comments in EPA's previous notices, and so has not addressed them again in this document. Readers should refer to EPA's policy statements of June 14, 1995 (60 FR 31300) and January 25, 1996 (61 FR 2378, 2386) for a full discussion of the issues.

Comment. Bayer, Valent, Rhone-Poulenc, and ACPA raised comments that had previously been raised in response to EPA's proposed revocation of 26 section 409 FARs, on the grounds that they violate the Delaney Clause. (59 FR 33941, July 1, 1994). Many of the comments suggested that EPA has incorrectly applied the legal standard ''induce cancer'' because EPA failed to duplicate prior FDA practice. The commenters contend that EPA's application of the standard was not sufficiently thorough and that EPA had failed to consider relevant evidence of biologic and mechanistic data, and the relevance of the results of animal studies to humans. The commenters also assert that EPA failed to take account of the fact that an ''induce cancer'' finding is appropriate only where the evidence is ''conclusive'', and that this high standard cannot be met, by definition, where EPA has classified a chemical as a Group C carcinogen. A Group C carcinogen is one for which the evidence of carcinogenicity is based on limited animal evidence that is normally judged to represent insufficient evidence to support the determination that a chemical is known to cause or can reasonably be anticipated to cause cancer in humans.

EPA response. EPA has previously responded at length to the issues raised by the commenters. Rather than repeat the arguments and EPA's response

verbatim, a summary of EPA's response follows. Readers should refer to EPA's March 22, 1996, Final Revocation of Pesticide Food Additive Regulations for a complete discussion of the issues. (61 FR 11994, and 12000–12002, March 22, 1996).

EPA believes its application of the ''induce cancer'' standard and the weight of the evidence approach has sufficiently addressed all relevant evidence. Where commenters have raised questions concerning how specific data were considered for specific chemicals, EPA has in this notice or in the docket responded to those comments.

EPA does not believe that it is required to conclude that the carcinogenicity found in the animal studies is relevant to humans, in order to conclude that the Delaney clause applies. Once a finding of animal carcinogenicity is made the operation of the Delaney clause is ''automatic.'' *Public Citizen v. Young*, 831 F.2d 1108, 1121 (D.C. Cir. 1987), cert. denied, 485 U.S. 1006 (1988). The D.C. Circuit has previously concluded that the Delaney clause indicates that ''Congress did not intend the FDA to be able to take a finding that a substance causes only trivial risk in humans and work back from that to a finding that the substance does not 'induce cancer in . . . animals.'' *Id*. Similarly, EPA may not work back from a conclusion that the results of an animal study are irrelevant to humans to a finding that the substance does not induce cancer in animals. *Id*.

EPA believes that mechanistic and biologic information may be relevant to the Delaney clause determination on animal carcinogenicity to the extent such information bears on the question of whether a substance induces cancer in the test animal. Some mechanistic and biologic information may have particular relevance to the issue of causation. However, having said that, EPA recognizes that proper evaluation under the Delaney clause of mechanistic and biologic information poses difficult questions. EPA does not believe that EPA or FDA has ever squarely decided this legal question in taking final action on a substance under the Delaney clause. Nor does EPA believe that question needs to be addressed in this notice. Although secondary mechanism arguments have been raised as to several of the pesticides at issue in this notice, as discussed below, EPA has decided either as a factual matter those arguments are not adequately supported or that there exists other evidence showing cancer induction independent from any cancer produced through a secondary mechanism.

EPA also disagrees that section 409 and FDA precedent hold EPA to an unusually high standard to support a finding that a substance induces cancer for purposes of the Delaney clause. Neither the statute nor FDA precedent support using any other than the general administrative standard of proof which is generally described as a preponderance of the evidence. The relevant words of the statute bar the establishment of a regulation for a food additive ''found to induce cancer when ingested by man or animal . . .'' The plain language of the statute certainly does not impose some extraordinary level of proof.

Comment. Valent and Bayer argue that ''Congress, the courts and FDA—the agency that has administered the clause the longest and most often—have all recognized that the [Delaney] Clause simply does not apply when the results of animal studies create merely the suggestion that a substance induces cancer.'' The commenters argue that the studies upon which EPA relied to make its determination that triadimefon and acephate induce cancer in animals are so seriously flawed that they merely ''suggest'' the induction of cancer. The commenters further argue that the General Food Safety clause in section 409 would instead apply, and cites the legislative history of section 409 and FDA's decision regarding the artificial sweetener cyclamate as support.

EPA Response. The commenters' argument is premised on the assertion that the Delaney clause imposes an unusually high burden of proof. As noted above, EPA disagrees with this assertion.

EPA also disagrees with the commenters' assertion that the studies on which EPA based on its finding of animal carcinogenicity create merely the suggestion that triadimefon and acephate induce cancer in animals. EPA believes that the studies provide positive evidence to support the finding that the pesticides induce cancer in animals.

However, if the commenters are correct that the data are fatally flawed, then EPA lacks the data to demonstrate that acephate and triadimefon are ''safe'' for purposes of either the general safety clause or the Delaney clause. Since the FFDCA places the burden of demonstrating the safety of the product on the proponent of the 409 tolerance, the lack of reliable data to support the tolerance would still result in revocation of the 409 tolerance under either clause.

Comment. Bayer commented that EPA has denied them procedural due process by proposing to revoke the 409 tolerance without simultaneously proposing to revoke the corresponding 408 tolerances and to cancel the corresponding pesticide use under FIFRA sec. 6. Bayer asserts that, as a result of EPA's coordination policy, revoking a section 409 on Delaney grounds is tantamount to a de facto revocation of the 408 tolerance and cancellation of the use under FIFRA, and that EPA has failed to make the requisite findings and to comply with the procedural requirements necessary to complete such actions.

EPA response. EPA disagrees that revoking a 409 tolerance is tantamount to a de facto revocation of the underlying 408 tolerance and to cancellation of the use. The revocation of a 409 tolerance does not, in itself, affect the status of a 408 tolerance or a pesticide registration. Nor does the revocation of a 409 tolerance have the effect of revoking the 408 or cancelling the registration. Revocation of a pesticide's 409 tolerance does not prevent raw food with residues of the pesticide from travelling in commerce, nor does it prohibit farmers from using the pesticide on a particular crop.

Moreover, it is not clear that revocation of a 409 tolerance would necessarily have an effect on the processed commodity. A 409 tolerance allows processed ready-to-eat food to travel within commerce when pesticide residues exceed the levels permitted by a 408 tolerance. If residues remain within the levels permitted by the 408 tolerance, processed food may legally continue to travel in commerce under the flow-through provision of section 402(a)(2), regardless of whether a 409 tolerance exists. Until EPA finally revokes the 408 tolerance or cancels use on wheat, conceivably no impact may be felt from revocation of the 409 tolerance.

With regard to triadimefon, it is unclear that revocation of the 409 tolerance would have any impact. Bayer asserted that triadimefon residues in wheat bran fall within the 408 tolerance, and that no triadimefon residues were found in routine FDA monitoring the processed food; if that is accurate, then revocation of the 409 tolerance should have no effect on the current status of wheat bran.

EPA has complied with all of the procedural requirements of the FFDCA in revoking the 409 tolerance and in proposing to revoke the 408 tolerance for triadimefon on wheat. See 61 FR 8174 (March 1, 1996)(FRL–5351–6). Further, EPA has clearly stated its policy on coordination between FIFRA and the FFDCA (January 25, 1996, 61 FR 2378). Congress has charged EPA with

administering two statutes with different procedural schemes. As discussed in EPA's coordination policy, EPA has taken an approach which harmonizes the two statutory standards to the extent possible. FIFRA does not require EPA to take action under FIFRA before acting under the FFDCA. Nor does EPA believe that the rulemaking procedures in the FFDCA violate Constitutional due process.

Comment. Bayer also commented that EPA would bear the burden of proof in any hearing under sections 409 or 408 of the FFDCA or under section 6 of FIFRA. To support this, the commenter cited *Director, Office of Workers' Compensation Programs, Department of Labor v. Greenwich Collieries*, 114 S Ct 2251 (1994). According to the commenters:

> Section 7(c) of the APA is controlling in food additive hearings, as the FFDCA is silent with regard to the burden of proof and other procedural issues, and exemptions to the APA are not lightly presumed. As such, the holding in *Greenwich Collieries* applies with equal force and effect to hearings held by EPA under section 409(f)(1) of the FFDCA. As the proponent of the revocation action, the agency bears the burden of persuasion and cannot shift that burden to Bayer or any other party objecting to the revocation action. EPA's procedural rule, 40 CFR 179.91, which provides for a contrary result is implicitly overruled by the holding in Greenwich Collieries.... Indeed, the holding in *Greenwich Collieries*, supra, applies with equal force and effect to hearings held pursuant to FFDCA section 408 and FIFRA section 6. EPA's procedural rules 40 CFR 164.80 and 179.91, and case law which provide for a contrary result are implicitly overruled. (Bayer Comments, 46–48)

EPA response. EPA disagrees that section 7(c) of the Administrative Procedures Act (APA) governs the allocation of the burden of proof in food additive hearings. EPA believes that both the FFDCA and FIFRA clearly allocate the burden of persuasion to the proponent of the registration or the tolerance. Consequently, EPA also disagrees that the holding in *Greenwich Collieries* has implicitly shifted the ultimate burdens of proof and persuasion in a hearing under either the FFDCA or FIFRA, from the proponents of a tolerance or a registration.

The Supreme Court did not consider the FFDCA, FIFRA, or EPA's regulations allocating the burden of proof in *Greenwich Collieries*. The court only examined the question of whether section 7(c) of the APA, in providing that the proponent of a rule or order has the burden of proof, has allocated to the proponent merely the burden of going forward or whether it has also allocated to the proponent the burden of persuasion. The court also considered whether section 7(c)'s allocation of the burden of proof applies to adjudications under the Longshore and Harbor Workers' Compensation Act (LHWCA) and the Black Lung Benefits Act (BLBA). The Court held that section 7(c) did allocate both the burdens of production and persuasion, and that section 7(c)'s allocation applied to both the LHWCA and the BLBA finding that both statutes explicitly incorporated section 7(c) of the APA.

Section 7(c) of the APA provides that ''[e]xcept as otherwise required by statute, the proponent of a rule or order has the burden of proof.'' As both statutes place the burden squarely on the proponent of registration and of permitting pesticide residues, of demonstrating that the pesticide product and its residues meet the statutory standards, both the FFDCA and FIFRA fall within the exception specified in section 7(c).

The legislative histories of both statutes clearly demonstrate that Congress intended to place the burden of demonstrating the safety of the product on the proponents of a registration or a tolerance. *e.g.*, H.R. Rep. No. 1125, 88th Cong., 1st Sess., 2 (1964); H.R. Rep. No. 1385, 83d Cong., 2d Sess., 5 (1954); S. Rep. No. 1635, 83d Cong., 2d Sess., 4 (1954). Case law also supports EPA's interpretation that section 7(c) of the APA does not apply to FIFRA or the FFDCA. e.g., *Environmental Defense Fund v. EPA*, 548 F.2d 1012, 1015 (D.C. Cir. 1976)(Supplemental Opinion on Petition for Rehearing)(''We hold that in light of the legislative history of FIFRA, and the numerous cases holding that its 1964 amendment was specifically intended to shift the burden of proof from the Secretary to the registrant, this case is one where the allocation of the burden of proof is, in the language of the APA, 'otherwise provided by statute.''); *Environmental Defense Fund v. U.S. Dept. of Health Education and Welfare*, 428 F.2d 1083,1087, 1092, n.27 (''In light of Congress' strong concern about the safety of pesticide residues and the congressional intent to place the burden of persuasion on those proposing to permit a residue to remain, the fact that the present petition seeks revocation of an existing tolerance does not affect the burden of persuasion established by Congress.... Once new evidence bearing on the safety of pesticide residues has been adduced or cited sufficient to justify reopening the validity of existing tolerances, as in the present case, the burden of establishing the safety of any tolerances remains on those who seek to permit a residue.'').

Comment. Valent and Bayer assert that EPA has failed to conduct a weight of the evidence review of their chemicals, but is merely relying on the classification of acephate and triadimefon as ''C'' carcinogens, which fails to meet the ''high degree of certainty necessary to conclude that a chemical induces cancer within the meaning of the Delaney clause, and is inconsistent with EPA's previous acknowledgment that a Group C classification doesn't equate to a finding that a chemical is either an animal carcinogen or induces cancer under the Delaney clause. To support the statement that EPA's assessment is inconsistent with previous statements, the commenters cite to EPA's policy statement, Regulation of Pesticides in Food: Addressing the Delaney Paradox (53 FR 41104, October 19, 1988) and the final rule revoking the 409 tolerance for dicofol (59 FR 10994, March 9, 1994).

EPA response. EPA's determination that triadimefon and acephate induce cancer is based on a weight-of-the-evidence review of all available studies for triadimefon and acephate, not merely on the fact that EPA had previously classified the chemicals as Group C carcinogens. And as noted above, EPA does not agree that the Delaney clause imposes a burden of certainty on the Agency greater than a preponderance of evidence.

Moreover, the commenter's use of the two notices to support its assertion is misleading. As EPA acknowledged in the dicofol revocation cited by the commenter, EPA believes that the language from the 1988 Delaney policy statement referred to by the commenter has only limited relevance to current decisions because that notice dealt primarily with whether certain types of pesticides in Group C would come within a de minimis exception to the Delaney clause. EPA continues to believe, as acknowledged in the dicofol revocation notice referred to by the commenters, that it is necessary to carefully examine pesticides classified in Group C according to the Cancer Assessment Guidelines to determine whether they meet the Delaney clause's induce cancer standard, which is exactly what EPA has done in concluding that triadimefon and acephate induce cancer.

Comment. Bayer and Valent assert that the proposed classifications of triadimefon and acephate are inconsistent with previous EPA actions, and are therefore, legally insupportable. The commenters point to more recent reviews by EPA of pesticides with ''comparable data'' that have classified those compounds as Group D

carcinogens, or that have ''otherwise resolved concerns.'' Specifically, the commenters cite EPA's decisions to establish tolerances for primisulfuron-methyl (55 FR 21547, May 25, 1990), hexazinone (55 FR 15104, March 22, 1995)(FRL–4935–1), quizalofop-p ethyl ester (57 FR 24553, June 10 1992) and bromoxynil (60 FR 16111, March 29, 1995)(FRL–4944–7).

EPA Response. The focus of both Bayer's and Valent's comments appears to be that EPA has been inconsistent in how it classifies pesticides with ''comparable'' data as carcinogens. Bayer suggests that were triadimefon to be evaluated in the same manner as pesticides with comparable data, or against current scientific standards, it would be classified as a Group D (insufficient data to classify) rather than as a Group C carcinogen. Bayer did not elaborate on what study observations or Agency determinations for the cited pesticides it considered ''comparable.'' However, its citations are presumably intended to bolster its point.

Valent, in similar but more extensive comments, detailed the Agency's findings on mouse liver tumors observed for quizalofop-ethyl, primisulfuron-methyl and hexazinone (bromoxynil was not mentioned in Valent's comment). Valent raised points concerning the type of tumors (malignant/benign), the dose levels at which tumors were observed (the MTD was exceeded), the historical incidence of liver tumors in mice, the statistical significance of the findings (trends versus pairwise comparisons), and other specific factors that it believes illustrate EPA's lack of consistency in its cancer classifications.

As a scientific matter, a weight-of-the-evidence approach to determining the classification of a carcinogen is inherently inexact. A number of factors must be considered, including all those mentioned by Valent, and these factors weighed against each other. Thus, even with apparently comparable data, under a weight-of-the-evidence approach, it is scientifically valid and even to be expected that EPA should arrive at different conclusions that lead to different cancer classifications. EPA's cancer peer review documents explain the relevance of each factor in EPA's classification decision.

However, the finding that a pesticide ''induces cancer in man or animals'' within the meaning of the Delaney clause is more straightforward and less scientifically onerous, since it requires only a finding of carcinogenicity in animals. Since cancer studies are conducted using animals, the data can directly demonstrate whether a pesticide does or does not result in cancer in animals. The cancer classification system used by EPA since 1986, on the other hand, focusses on cancer risk to humans. It is entirely possible that EPA could determine that a pesticide classified as a Group D carcinogen (insufficient data for humans) meets the ''induce cancer'' standard for animals. Under the Delaney clause, this is all that is required.

Accordingly, EPA disagrees with comments purporting to find flaws in EPA's ''induce cancer'' determination based on perceived inconsistencies in cancer classification for humans or comparability of cancer profiles within the classification system. Notwithstanding differences in classification among acephate, triadimefon and other chemicals apparently similarly situated, a preponderance of the evidence demonstrates that both triadimefon and acephate induce cancer in animals.

In the case of triadimefon and acephate, however, EPA classified those chemicals as C carcinogens based upon stronger evidence of carcinogenicity than was found with the four pesticides cited by Valent and Bayer as having comparable cancer profiles but which were classified only as Group D carcinogens. For both acephate and triadimefon, liver tumors were observed in a pairwise manner at dosages that were not determined to be excessive. In the case of acephate, the tumors were heavily malignant in female mice. In the case of triadimefon, although only benign adenomas were seen, they were found in a pairwise comparison in both sexes at doses clearly under the MTD.

In each of the other cases, either the tumors were observed only at excessive doses (primisulfuron-methyl and quizalofop-ethyl) or showed only a trend for liver tumors that was not statistically significant upon pairwise comparison (hexazinone). A trend for expression of tumors is a less significant finding than a pairwise comparison and would not in itself normally lead to a positive cancer classification. Although Bayer claims that EPA had determined that bromoxynil is a Group D carcinogen, EPA has always classified bromoxynil as a Group C carcinogen. The FIFRA Scientific Advisory Panel recommended a Group D classification, which EPA did not adopt.

Comment. Bayer also argued that EPA has applied a ''shifting definition of what it means to 'induce cancer' for purposes of the Delaney clause,'' citing the final regulation revoking 409 tolerances for benomyl, mancozeb, phosmet and trifluralin (58 FR 37863, July 14, 1993), the proposed revocation for several 409 tolerances found to be inconsistent with the Delaney clause (59 FR 33942, July 1, 1994), and the proposed revocation for triadimefon (60 FR 3608, January 18, 1995).

EPA response. It is true that the definition of ''induce cancer'' in the first two notices referred to by the commenter do not include, as cancer, the class in which only benign neoplasms occur. However, EPA disagrees that this is a substantive change to its interpretation of ''induce cancer.'' EPA's interpretation is supported by the court in *California v. Browner*, which agreed that the change was not substantive. No.Civ. S–89–0752, slip op. at 5 (E.D. Cal. Feb. 1995)

VIII. Comments Related to Specific Pesticides

A. Acephate

Comment. Valent contended that acephate does not induce cancer because the MTD was exceeded in the mouse study, and that testing at lower dose levels which showed no evidence of carcinogenicity should be used. Valent also proposes a secondary mechanism for carcinogenesis of acephate, based on upon a theory that acephate at high doses alters the homeostasis of female mice such that they are phenotypically similar to male mice in their expression of liver tumors.

EPA Response. EPA believes that the high dose used in the study represents an MTD that was well-tolerated by the test animals. Moreover, the toxicity seen at the high dose level does not alter the finding of malignant liver carcinomas at that dose. With respect to the hypothesis that acephate causes female mice to respond as if they were male mice, Valent provided little support for this hypothesis. Moreover, it is uncertain that this hypothesis has been peer reviewed or found acceptance in the scientific community. In the absence of any data to support its contentions, EPA believes that the acephate induces cancer in animals.

Comment. Valent also raised a number of points concerning the individual mutagenicity studies for acephate, suggesting that they are flawed by today's scientific standards, and thus do not support an induce cancer determination.

EPA Response. Although individually, Valent's points may have merit, the mutagenicity data base is considered in its entirety and only in a supporting capacity to a determination of carcinogenicity. That is, while positive evidence of genotoxicity may support a weight of evidence finding that a pesticide is carcinogenic, the lack

of a complete mutagenicity data base, or deficiencies or negative results in individual mutagenicity studies, do not negate positive cancer findings in other studies. Acephate's mutagenicity studies, while perhaps less than optimal by today's standards as noted by Valent, overall showed consistently positive responses in in vitro studies, and in any case do not negate the clear finding that acephate induces cancer in animals.

Comment. Valent argued that the 409 tolerance for acephate is not needed, for several reasons. Valent argues that EPA improperly requires a 409 tolerance for every use in a food handling establishment without regard to whether residues actually occur. They further state that use of acephate does not result in finite residues, that no finite residues have ever been found, and that EPA's establishment of the 409 tolerance at the level of quantification implicitly recognizes that no residues are expected to be present. Finally Valent states that, since the 409 tolerance is not needed, the use of acephate need not be cancelled, and that it is in the public interest to retain the use.

EPA Response. Contrary to Valent's assertion, EPA does not ''automatically'' require a food additive tolerance for all pesticides used in food handling establishments. EPA considers the nature of the pesticide and how it is applied in determining whether residues are likely to result in food, and therefore that a 409 tolerance is needed. For example, an insecticidal bait enclosed in a ''bait station'' would normally not require a 409 tolerance because the use is not likely to result in residues in food. Bait station uses in which the pesticide is contained are, however, a far cry from typical food handling establishment insecticide applications, which are applied in an relatively uncontained manner through sprays and dusts. While a crack and crevice treatment (such as that for acephate) may be less likely to result in residues in food than a broad general treatment, EPA believes that there is sufficient likelihood that residues may occur from crack and crevice treatments that the pesticide is a food additive for which a 409 tolerance will normally be needed.

Valent goes on to assert that ''no detectable residues have ever been found'' in food, and would not be expected to result from its use pattern. Valent cited in support of its contention a 1981 study in which acephate was applied at twice the maximum label rate, and residues were not found above the limit of detection.

However, in this study, residues were found in some samples at close to the detection limit. At an application rate of 1 percent active ingredient, residues were found in lettuce at 0.02 ppm and in cheese at 0.009 ppm, at or close to the limit of detection of 0.01 ppm. At 2X rates, quantifiable residues were found in lettuce (0.034 ppm), meat (0.016 ppm), bread (0.023 ppm) and apple juice (0.011 ppm), all above the limit of detection. Thus at a 2X rate, finite residues at or above the level of detection can be expected. Valent's study clearly demonstrates that quantifiable residues can result in at least some foods at label rates. It is difficult to argue that these data demonstrate that residues are not likely to be present.

For several reasons, EPA believes that it needs a demonstration of no residues using highly exaggerated rates (considerably higher than 2X) to be persuaded that there is no reasonable expectation of residues in food such that a 409 tolerance is not needed. First, food handling establishments cover a wide range of operations, from processing facilities such as bakeries, canneries and dairies, to restaurants and grocery stores. Thus the circumstances under which food might be exposed to the pesticide may vary considerably in a manner that is difficult to capture in a single residue study. Second, EPA requires residue studies using a representative but relatively limited set of foods, which is necessary given the number and variety of foods that may be present in a food handling establishment and the impracticality of determining residues for all foods individually.

Valent cites its label instructions and admonitions as further support of their contention that the use pattern would not be expected to lead to residues in food. Even within the permissible label instructions, however, the actual application of the pesticide may vary. Applicators may mix and apply the pesticide differently, using application equipment and techniques that lend themselves to higher amounts of actual pesticide deposited. Moreover, the applicator's ability to physically control the application so as to comply with label admonitions about food and surface contact may be highly variable. While label instructions and warnings if followed will minimize the possibility that the pesticide will contact food or food surfaces, they still allow considerable judgment and skill on the part of the applicator. The applicator cannot know the extent to which he has been successful in his efforts to ''avoid contamination of food'' or to ''use care to avoid depositing the material onto exposed surfaces or introducing the material into the air.'' EPA cannot rely on the fact of label instructions as assurance of success in precluding residues in food, particularly in light of data that demonstrate actual residues in food from application according to label instructions.

Moveover, the presence of residues from a particular application is not totally dependent on how well the applicator can comply with label instructions. Factors unrelated to the application itself, and therefore unrelated to label instructions, may contribute equally to residues in food. Environmental factors such as temperature, humidity, and ventilation, and product characteristics such as volatility cannot be controlled by the applicator. Therefore, label instructions alone are not sufficient proof that residues will not result from application.

EPA categorically rejects Valent's claim that EPA's use of the level of quantitation as the numerical tolerance level implies that EPA believes that there is no reasonable expectation of residues from use of acephate in food handling establishments. EPA has never so stated. Moreover, the data cited by Valent in its comments indicate that residues close to the detection limit of the analytical method are possible under actual use conditions. The Agency believes it is appropriate in these circumstances to set numerical tolerance limits, especially considering the potential variability in foods, exposures, and application that may result in quantifiable residues. Accordingly, tolerances are established at the limit of quantitation of the analytical method. This is a logical approach to the regulation of residues generally in food handling establishments, and cannot be read as supporting any EPA belief that residues are unlikely to occur.

Finally, since EPA believes that use of acephate requires a 409 tolerance which is not permitted under the Delaney clause, arguments concerning public health considerations or the benefits of use are not relevant to EPA's decision to revoke the FAR for acephate. The Delaney clause does not permit such considerations.

B. Triadimefon

Comment. Bayer comments that a 409 tolerance on milled fractions of wheat is unnecessary, because milled fractions of wheat are not ready-to-eat.

EPA response: EPA considers that milled fractions of wheat, or wheat bran, are ready-to-eat human food, as EPA noted in its notice proposing to revoke

the 408 tolerance for wheat (61 FR 8189, March 1, 1996).

Comment. Bayer argues that the residues of triadimefon do not concentrate above the 408 tolerance, and thus EPA should revoke the 409 tolerance on the grounds that it is unnecessary. Bayer asserts that EPA based its determination that a 409 tolerance for triadimefon was necessary on processing studies that do not reflect the current label of the registered pesticide product, and that EPA has failed to consider the degree to which triadimefon residues are further diluted by mixing and blending with untreated wheat, and by further dissipation of residues during the time the food leaves the processor until it reaches the supermarket shelf.

To prove that residues in wheat bran do not exceed the 408 tolerance, Bayer relies on ''extensive monitoring data'' conducted by industry and FDA to support its argument, and points generally to 27 FDA market basket surveys and samples collected under FDA's regulatory monitoring program. More specifically, Bayer asserts that as part of its routine monitoring, FDA tested 86 samples of whole grain wheat and 178 various food forms of wheat for levels of triadimefon between the years of 1985–1992. None of the 264 samples contained residues of triadimefon above the analytical limit of quantification. Bayer asserts that these data are ''slanted towards high residue situations'' and thus are ''worst case surveillance conditions.''

Finally, Bayer argues that EPA is legally required by the language of the flow-through provision and the statutory definition of a food additive to determine whether a 409 tolerance is needed based on the measured residues on the actual commodities and not on theoretical calculations that do not reflect actual use practices or label requirements. All of the commenters raised some variant of this argument in their comments. According to Bayer, the definition of a food additive requires that the intended use of a substance must actually result in, or reasonably be expected to result in, directly or indirectly, the substance becoming a component of food. Based on the current label for triadimefon and based on the likelihood of additional dilution and degradation of residues from current processing methods, Bayer asserts that EPA can have no reasonable expectation that triadimefon residues will be present in processed foods at levels above the 408 tolerance.

EPA Response. EPA disagrees with the commenter's assertion that EPA improperly failed to consider several factors that could result in significantly diluted residues in wheat bran and that EPA improperly relied on studies that do not reflect current triadimefon use practices. EPA based its determination that triadimefon residues in wheat bran were likely to exceed the 408 tolerance on processing studies demonstrating that triadimefon residues were present at higher levels in wheat bran than in wheat.

EPA has considered that triadimefon residues will be diluted by mixing and blending of treated wheat. In accordance with the policy discussed in its June 1995 policy statement (60 FR 31305, June 14, 1995), EPA compared the highest average residue values from field trials times the concentration factor to the 408 tolerance, and determined that residues in wheat bran would likely exceed the 408 tolerance. As EPA noted above, the average concentration factor in the processing of milled fractions of wheat is 3.7 and the HAFT for triadimefon on wheat is 0.14 ppm. Because multiplying the average concentration factor by the HAFT exceeds the adjusted section 408 tolerance for triadimefon on wheat (0.2 ppm), EPA believes that it is likely that some milled fractions will contain residues exceeding the 408 tolerance.

It is true that EPA did not consider the extent to which farmers may be applying triadimefon at lower rates, or the extent to which wheat bran containing triadimefon residues is mixed with wheat containing no residues, but for the reasons discussed at 60 FR 31302–31306, EPA has determined that such considerations would be inappropriate. It is also true that EPA did not consider further degradation of residues during the time the food leaves the processor until the moment it is actually eaten, but it is not apparent how EPA could take this into account, other than to the extent the effects of degradation are captured in the processing study. In any event, if wheat bran at one stage of its production and marketing has residues that exceed the 408 tolerance, it is no defense to a charge of adulteration that at some later time in the production and marketing scheme residues will be below the 408 tolerance. EPA has also previously discussed the rationale for this decision at length in 60 FR 31305.

Further, EPA does not conduct studies to support the registration or tolerance for a particular pesticide. FIFRA and the FFDCA clearly place that responsibility on the manufacturer seeking to register or to establish a tolerance for a pesticide product. To the extent that EPA is relying on data that Bayer believes no longer reflects actual conditions of triadimefon use, it is Bayer's responsibility to submit new processing studies that accurately reflect whether triadimefon is likely to concentrate above the 408 tolerance. Under the statutory scheme, which requires EPA to rely on data conducted by manufacturers to determine whether a tolerance level is safe, EPA is legally justified in basing its regulatory decisions on the data presented to it. Should Bayer submit new processing studies EPA will consider the data, as appropriate.

As EPA has previously noted at 60 FR 31305–31306, the Agency bases its concentration determinations primarily on whether processing studies show that the processing of a commodity results in a level of residues in the processed food which is greater than the level of residues in the raw food. However, EPA has acknowledged that it would consider data from marketplace studies and FDA monitoring, where circumstances permit. The relevance of marketplace studies, however, would depend on how the marketplace study was conducted. For example, the principal reason marketplace studies have been conducted in the past is to obtain better data concerning actual residue values close to the point at which food is consumed. Thus, marketplace studies generally involve sampling commodities in retail grocery stores. A tolerance for processed food would not only apply to foods in retail stores, but at all prior points at which the food moved in interstate commerce. This fact would need to be taken into account in assessing the relevance of a marketplace study in determining the likelihood of residues in processed food in excess of the 408 tolerance.

Monitoring data can also be relevant to determining the likelihood of processed food exceeding the 408 tolerance. However, FDA monitoring data, especially monitoring data on processed foods, generally have been limited and thus may not be a reliable predictor of the level of residues of triadimefon in milled fractions of wheat. The monitoring referred to by the commenter is not so thorough and reliable that it would cause EPA to ignore the results of the processing studies.

Comment. Bayer contends that triadimefon does not induce cancer because the high doses used in both rat and mice studies exceeded the maximum tolerated dose (MTD), and thus tumors seen at these levels are not related to administration of triadimefon. Bayer also asserted that the mid-dose level of these studies did provide an adequate MTD for purposes of

evaluating the carcinogenic potential of triadimefon. Therefore Bayer argues that carcinogenic potential should be evaluated on the basis of the findings at the mid-dose level rather than the purportedly excessive high dose level. Bayer also cited the fact that mutagenicity studies showed that triadimefon is not genotoxic or mutagenic.

EPA Response. EPA disagrees with Bayer that the data from the high dose were not appropriate to consider in making the ''induce cancer'' determination, and also that the mid-dose was adequate in these studies. In both the rat and mouse studies, the high dose (1800 ppm) is considered adequate because there were no signs of excessive toxicity at that level. Moreover, the mid-dose level in each study (300 ppm) was not considered adequate as an MTD because the effects seen at that level were relatively minor increases in liver enzyme levels and liver weight, as well as slight to moderate liver hypertrophy and cell changes. EPA does not consider these changes adequate to demonstrate that an MTD has been achieved. By comparison, at the high dose level (which still did not show excessive toxic effects), liver effects were more pronounced, and included (in the rat) increased food consumption, increased fat in the liver, significant physiological and cellular changes in liver cells and formation of hyperplastic nodules. Similar evidence of increased liver damage was seen in the mouse at the high-dose level.

As stated in EPA's response on acephate, mutagenicity studies are considered only supporting evidence of carcinogenicity and do not negate clear evidence of carcinogenicity from other studies.

Comment. Bayer argued that the increase in follicular cell thyroid adenomas seen in the rat study occurred as a result of a hormonal effect, an increase in thyroid stimulating hormone, and thus is not directly caused by the triadimefon.

EPA Response. In its final notice revoking tolerances for mancozeb on oat bran (March 22, 1996, 61 FR 12003), EPA noted that the legal relevance of secondary mechanisms claims to the Delaney clause ''induce cancer'' finding has not been resolved. In that notice EPA also specifically discussed whether thyroid tumors could be demonstrated to occur via a secondary mechanism and the scientific information needed to support such a contention. Bayer has submitted no such information. EPA reiterates its position on thyroid tumors as stated in that notice. With respect to triadimefon, EPA has determined that, independent of any possible secondary mechanism that might be operating for the thyroid adenomas, the hepatocellular adenomas were related to the administration of triadimefon, and thus the question of a secondary mechanism need not be addressed.

C. Iprodione

Comment. Rhone-Poulenc argued that a 409 tolerance for iprodione in raisins is not required because (1) raisins should be classified as a RAC; and (2) because, even if not a RAC, iprodione does not concentrate in raisins above the 408 tolerance for grapes.

EPA Response. As noted in Unit VII, these revocations were proposed before EPA modified its tolerance policies in June 1995 and January 1996. Comments on the RAC status of dried commodities have been addressed in the Agency's interpretive policy of January 25, 1996 (61 FR 2386), in which EPA concluded that raisins are a processed food because they are dried for the purpose of creating a new marketable commodity, and not incidental to storage or transportation needs of the raw agricultural commodity grapes.

With respect to the assertion that residues in grapes do not concentrate in raisins, Rhone-Poulenc cited studies previously submitted in 1982 and 1983 in which residues in raisins did not exceed the current 60 ppm tolerance in grapes. Rhone-Poulenc, however, failed to note in its comments that in 1994, it petitioned EPA to reduce the tolerances for both grapes (from 60 ppm to 10 ppm) and raisins (from 300 ppm to 50 ppm). In conjunction with the petition and to satisfy reregistration data requirements, Rhone-Poulenc submitted additional residue data. These data show that the HAFT for grapes is 4.1 ppm, and the average CF, based on 8 sets of processing studies, is 3.56. The simple calculation of likely residues in raisins, therefore (4.1 ppm X 3.56 = 14.6 ppm), shows that residues would exceed the proposed 10 ppm tolerance in grapes. As noted in Unit III, EPA is using its latest residue data to inform its decisions on revocation of tolerances under the Delaney clause.

Comment. Rhone-Poulenc raised secondary mechanism issues associated with iprodione, namely that Leydig cell tumors seen in male rats are caused by a ''mechanism operative only at the high test doses'' and the ovarian tumors observed in female mouse studies are caused by ''a prolonged and profound perturbation of sex hormone regulation at the target organ level.'' Moreover, Rhone-Poulenc asserts that the Leydig cell tumors have no relevance to humans.

EPA Response. In neither case were supporting data submitted to demonstrate that these speculative mechanisms of action occur. In the absence of any evidence of the plausibility of the secondary mechanisms, EPA considers the observed tumors to be evidence that iprodione induces cancer in animals. EPA cannot judge the argument that Leydig cell tumors are not relevant to humans, since, from the data currently available to EPA, no specific mechanism of action of any hormonal alteration has been clearly characterized for iprodione. In any event, whether tumors observed in animals are relevant to humans has no bearing on a determination that iprodione induces cancer in animals.

Comment. Finally, Rhone-Poulenc also contended that liver tumors in mice were observed only at dose levels at the MTD.

EPA Response. EPA considers the dose level to be adequate (but not excessive) in both rat and mouse studies for the purpose of assessing carcinogenicity.

Commenters on acephate, iprodione and triadimefon all raised the issue of the MTD, and suggested that tumors observed only at dosage levels above the MTD should not be considered to support an ''induce cancer'' finding. Indeed, each suggested that unless tumors result at levels that do not express ''excessive'' non-cancer toxicity, EPA should reverse its finding that the pesticide induces cancer.

EPA Response. EPA disagrees in each case with commenters that dosage levels were excessive, and believes that the tumors are attributable to the pesticide in question.

IX. Procedural Matters

A. Filing of Objections and Requests for Hearings

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed 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 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).

Any person wishing to comment on any objections or requests for a hearing may submit such comments to the hearing Clerk on or before September 12, 1996.

B. Effective Date

This final rule is effective September 27, 1996. In addition, if EPA does not receive objections to this order, this order and the factual and legal basis for this order, become final and are not judicially reviewable. See section 409(g)(1), 21 U.S.C. 348(g)(1) and *Nader v. EPA*: 859 F.2d 747 (9th Cir. 1988), cert. denied, 490 U.S. 1931 (1989). For example, if an interested person disagrees with a necessary finding in this order but agrees with the outcome, that person must file timely objections to that finding in this order; if no objection to the finding is made, the finding will become final for purposes of any future proceedings to which that finding is relevant.

C. Request for Stays of Effective Date

A person filing objections to this final rule may submit with the objections a petition to stay the effective date of this final rule. Such stay petitions must be submitted to the Hearing Clerk on or before August 28, 1996. A copy of the stay request filed with the Hearing Clerk shall be submitted to the Office of Pesticide Programs Docket Room. A stay may be requested for a specific time period or for an indefinite time period. The stay petition must include a citation to this final rule, the length of time for which the stay is requested, and a full statement of the factual and legal grounds upon which the petitioner relies for the stay. In determining whether to grant a stay, EPA will consider the criteria set out in the Food and Drug Administration's regulations regarding stays of administrative proceedings at 21 CFR 10.35. Under those rules, a stay will be granted if it is determined that:

(1) The petitioner will otherwise suffer irreparable injury.

(2) The petitioner's case is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting the stay.

(4) The delay resulting from the stay is not outweighed by public health or other public interests.

Under FDA's criteria, EPA may also grant a stay if EPA finds such action is in the public interest and in the interest of justice.

Any person wishing to comment on any stay request may submit such comments and objections to a stay request to the Hearing Clerk, on or before September 12, 1996. Any subsequent decisions to stay the effect of this order, based on a stay request filed, will be published in the Federal Register, along with EPA's response to comments on the stay request.

D. Public Docket

A record has been established for this rulemaking under the docket number [OPP–300360B] (including any comments and data submitted electronically). 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 22202.

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 any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rule-making record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

X. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not ''significant.'' Nevertheless, EPA submitted this action to the Office of Management and Budget (OMB) for an informal review. Any changes made during that review have been documented in the public record.

Three of the 409 tolerances being revoked today because they violate Delaney (iprodione/raisins and ginseng and triadimefon/wheat) also have 408 tolerances. If the uses and 408 tolerances remain in effect without needed 409 tolerances (prohibited by the Delaney clause), lawfully treated foods could potentially be adulterated, and subject to seizure. In each case, however, EPA believes that there is little likelihood of adulterated food.

Raisins. Grapes grown for raisins are generally not extensively treated for *Botrytis* rot (the almost exclusive use of iprodione in California). Grapes intended for fresh market are more likely to be treated with iprodione because they may be exposed to late-season rain, or need protection against rotting in post-harvest storage. A grower whose grape crop is intended for raisins is likely to make that decision early in the season because of the differing cultural practices that are employed in fresh market production, and thus will not typically use significant amounts of iprodione.

Iprodione is used on approximately 9 percent of the total grape acreage in California. EPA has little information on use of iprodione segregated by the intended use of grapes, but estimates that iprodione is used on less than 4 percent of grapes intended for raisins, but up to 20 percent of grapes for fresh market use.

In 1994, total California grape production was 5.253 million tons of fresh grapes (California Agricultural Statistics Service, September 1995). Of that total, 36 percent was dried into raisins. If iprodione were applied equally to all grapes, regardless of ultimate use, a maximum of 170,200 tons of raisins containing iprodione residues could be estimated ($.09 \times .36 \times 5.253$ million tons). However, as noted, EPA believes this is a significant overestimate, since in typical years grapes intended for raisins would seldom be treated with iprodione. Similarly, in typical years, grapes grown for the fresh market would not be

expected to be diverted to the raisin market in large quantities, and all raisins produced from iprodione-treated grapes would not be expected to contain residues above the RAC tolerance. Accordingly, although EPA believes that revocation of the 409 tolerance for iprodione on raisins would result in some raisins being subject to seizure, the Agency estimates that the tonnage of raisins subject to seizure would not be substantial taking into account annual production figures. However, as noted earlier, evidence shows that some percentage of the grape crop is diverted to raisin production.

Wheat. Today's action does not affect the current 408 tolerance for wheat, which will remain in effect. As noted in Unit IV.E, EPA estimates that residues in wheat bran based on recent residue data can be expected to be as high as 0.5 ppm. While such residues would exceed an adjusted 408 tolerance of 0.2 ppm, they are not likely to exceed the existing 1 ppm tolerance. In any event, as noted in EPA's proposed revocation of the 408 tolerance for wheat (March 1, 1996, 61 FR 8174), triadimefon use on wheat is insignificant (generally in the range of 1 percent or less), and thus the potential for seizure of large amounts of wheat bran is low.

Ginseng. Today's action does not affect the current 408 tolerance for ginseng of 2 ppm (§ 180.399). EPA believes that, at this level, there may be some adulterated ginseng, but does not have sufficient information to estimate how much. Residue field trial data from Wisconsin (which produces 90 percent of ginseng) conducted at the maximum label rate and minimum pre-harvest interval (PHI) of 36 days indicate that residues in fresh and dried ginseng were below the 2 ppm RAC tolerance. Other data from North Carolina indicate that residues in dried ginseng could be as high as 3.3 ppm, but these data were based on a shorter PHI than allowed by the label. From this limited field trial data, EPA cannot determine whether the existing 2 ppm tolerance is adequate to cover residues in all dried ginseng.

Food handling establishments. For the purposes of this economic analysis, EPA has assumed that revocation of the 409 tolerance for use of acephate in food handling establishments results in the elimination of this use. EPA estimates that discontinuing the use of acephate in food handling establishments will cause negligible overall economic impact, since there are numerous cost-effective alternatives for insect control in food handling establishments.

Target pests in food handling establishments are cockroaches and stored product pests. Any impacts that would occur would most likely be where acephate is used for cockroach control, not for stored product insect control. For cockroach control alternatives include, but are not limited to, chlorpyrifos, cyfluthrin, boric acid, hydramethylnon, diazinon, propetamphos, and bendiocarb. Acephate has quick ''knockdown'' capability, and less resistance problems than most quick knockdown alternatives, but there are sufficient alternatives that EPA believes economic impacts from the loss of acephate will not be significant.

Barley. EPA is today revoking both raw food and processed food tolerances for triadimefon on barley because they are not needed. The impacts associated with the revocation of the 408 tolerance on barley are expected to be minimal because the use of triadimefon on barley was cancelled by the registrant in August 1993. EPA believes that the three years that have elapsed are sufficient for existing stocks of product and treated barley to clear channels of trade.

Citrus oil. For this 409 tolerance, the 408 tolerance and registered use will remain effective, and therefore, no impact is expected.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Agency must consider whether a regulatory action will have an adverse economic impact on small entities. Section 605(b) requires the Agency to either certify that the regulatory action will not have a significant economic impact on a substantial number of small entities, or prepare a regulatory flexibility analysis. For the reasons cited in Unit X.A. of this document, EPA certifies that this regulatory action does not impose significant adverse economic impacts on a substantial number of entities, large or small. Therefore, a Regulatory Flexibility Analysis is not required.

C. Paperwork Reduction Act

This order does not contain any information collection requirements subject to review by Office of Management and Budget under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

D. 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.

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.

E. Review by Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Food additive, Pesticides and pests.

Dated: July 18, 1996.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR Chapter I, Subchapter E, is amended as follows:

1. In part 180:

PART 180—[AMENDED]

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

§ 180.410 [Amended]

b. By removing from the table in § 180.410 the entries for ''Barley, grain,'' ''barley, green forage,'' and ''barley, straw.''

2. In part 185:

PART 185—[AMENDED]

a. The authority citation for part 185 continues to read as follows:

Authority: 2l U.S.C. 346a and 348.

§ 185.100 [Removed]

b. By removing § 185.100.

§ 185.800 [Removed]

c. By removing § 185.800.

§ 185.3650 [Removed]

d. By removing § 185.3650.

§ 185.3750 [Removed]

e. By removing § 185.3750.

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