ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 185

[OPP–300335A; FRL–5357–7]

Revocation of Pesticide Food Additive Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA has made a final determination regarding 26 food additive regulations (FARs) for 7 pesticides that were previously proposed for revocation on the grounds that the FARs violated the Delaney clause in section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). Today, EPA is revoking 13 FARs because they violate the Delaney clause and the remaining 13 FARs because they are not needed to prevent adulterated food.

EFFECTIVE DATE: This final rule is effective May 21, 1996.

ADDRESSES: Written objections, requests for a hearing, and/or requests for stays identified by the document control number OPP–300335A (FRL–5357–7), must be submitted by April 22, 1996, to the Hearing Clerk, EPA, 401 M Street, SW., Washington, DC 20460, with a copy to the OPP docket. Comments on objections, requests for a hearing, and/or requests for stays must be submitted by May 6, 1996 to the OPP docket: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Hand deliver to: Rm. 1132, CM 2, 1921 Jefferson Davis Hwy., Arlington, VA.

Information submitted as a filing 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 filings 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 (non-CBI) filings will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

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SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

A. 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. EPA was authorized to establish pesticide tolerances under Reorganization Plan No. 3 of 1970. 5 U.S.C. App. at 1343 (1988). 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 (USDA). EPA can establish a tolerance in response to a petition (FFDCA section 408(d)(1), 409(b)(1)), or on its own initiative (FFDCA sections 408(e), 409(d)).

The FFDCA has separate provisions for tolerances for pesticide residues on raw agricultural commodities (RACs) and tolerances on processed food. For pesticide residues in or on RACs, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408. 21 U.S.C. 346a. EPA regulates pesticide residues in processed foods under section 409, which pertains to ''food additives.'' 21 U.S.C. 348. Maximum residue regulations established under section 409 are commonly referred to as food additive regulations (hereafter referred to as ''FARs''). Section 409 FARs 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 section 408 raw food tolerance to flow through to the processed food forms. Thus, a section 409 FAR 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 prescribed for the RAC, or if the processed food itself is treated or comes in contact with a pesticide.

If a food additive regulation must be established, section 409 of the FFDCA requires that the use of the pesticide will be ''safe'' (21 U.S.C. 348(c)(3)). 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 demed safe if it has been found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer when ingested by man or animal.''

B. Regulatory Background

1. *Les* v. *Reilly*

On May 25, 1989, the State of California, the Natural Resources Defense Council, Public Citizen, the AFL-CIO, and several individuals filed a petition requesting that EPA revoke several FARs. The petitioners argued that these FARs should be revoked because they violated the Delaney clause.

EPA responded to the petition by revoking certain FARs, but retained several others on the grounds that the Delaney clause provides an exception for pesticide residues posing *de minimis* risk; EPA denied the petition with respect to the FARs determined to fall under this exception. EPA's response was challenged by the petitioners in the U.S. Court of Appeals, Ninth Circuit. On July 8, 1992, the court ruled in *Les* v. *Reilly*, 968 F.2d 985 (9th Cir.), *cert. denied*, 113 S.Ct. 1361 (1993), that the Delaney clause barred the establishment of a FAR for pesticides which ''induce cancer'' no matter how infinitesimal the risk.

In response to the court's decision in *Les* v. *Reilly*, EPA has taken steps to identify and revoke all section 409 FARs for pesticides which ''induce cancer.'' On March 30, 1994, EPA issued a list of pesticide uses which potentially could be affected by the court's decision (59 FR 14980). (Note that, for the purpose of today's document, this list has been superseded by appendices to the court-approved settlement in *California* v. *Browner*, discussed below.)

After revoking certain FARs of six pesticides that were the subject of the original NRDC petition, EPA decided to evaluate the remaining pesticide uses in phases. The first phase of proposed revocations was announced on July 1, 1994, and involved 26 FARs for seven pesticides (59 FR 33941; July 1, 1994). In today's notice, EPA is making final determinations regarding these 26 FARs.

2. *California* v. *Browner*

In a court-approved settlement, entered on February 9, 1995, in the case of *California* v. *Browner*, EPA agreed to make decisions regarding pesticides that may be affected by the Delaney clause. This settlement agreement includes a timetable for making the decisions. This document is consistent with the timeframes in that settlement.

C. Actions Since Proposed Rule

The National Food Processors' Association (NFPA) filed a petition with the EPA in September 1993. This petition challenged a number of policies under which EPA administers its tolerance-setting program. In the Federal Register of June 14, 1995 (60 FR 31300), EPA issued a partial response to the NFPA petition. In that document, EPA concluded that some changes were warranted to its policies concerning application of the Delaney clause, in particular the concentration and ''ready-to-eat'' (RTE) policies. On January 25, 1996, EPA completed its response to the NFPA petition by announcing its coordination policy and its interpretation of what constitutes a RAC (61 FR 2378). Section II of this preamble contains a summary of these policy changes.

D. Today's Action

The FAR revocations being made final in this notice were proposed on July 1, 1994 (59 FR 33941), before EPA had responded to the NFPA petition and adopted its new policies. In addition, EPA has received many petitions from the registrants of these pesticides requesting revocation of many of the FARs, on the basis that they are not needed. For each of these petitions, EPA has published a ''Notice of Availability and Request for Comments'', in the Federal Register. Today's final rule is consistent with EPA's new policies and, where appropriate, the decisions are based on the petitions rather than the proposed rule of July 1, 1994.

II. EPA's Policy Changes Since the Proposal

A. Concentration and Ready-to-Eat Policies

To determine whether the use of a pesticide on a growing crop needs a section 409 FAR in addition to a section 408 tolerance, EPA looks at the likelihood that the residue levels in the processed food when ready to eat will exceed the section 408 tolerance level. In the past, EPA applied this policy focusing almost exclusively on the results of processing studies using treated crops. In response to the NFPA petition, EPA announced new policies on how it would determine whether a pesticide needs a section 409 FAR (60 FR 31300, July 1, 1994). EPA stated that it would consider a greater range of information in determining the likelihood of residues in processed food exceeding the section 408 tolerance. EPA also adopted a definition of RTE as it applies to human food and animal feed. Whether a food is RTE or not is critical to application of the concentration policy. 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 section 408 tolerance.

Perhaps the most significant new information that EPA stated it would consider is information bearing on the average residue value from crop field trials. The data from field residue trials show that it is possible to obtain significantly different residue values from multiple field trials. EPA's old policy was to use the highest field trial sample value to calculate expected residues in the processed food. However, in response to the NFPA petition, EPA concluded that where a crop is mixed or blended during processing, it is appropriate to use an average of the residue levels from field trials, rather than the highest sample value in estimating the potential level of residue in processed food. As EPA noted, EPA believes that generally the most appropriate average value to use is the ''highest average field trial'' (HAFT) value, or the average of the highest values found in each of the field trials. Consequently, EPA revised its procedures and is now using the HAFT as the basis for determining whether a section 409 FAR is needed. Use of the HAFT for food commodities that are likely to be mixed or blended decreases the likelihood that residues in processed food will exceed the section 408 tolerance.

In addition EPA has revised its policies for the use of multiple processing studies. EPA may receive several processing studies for a crop, with each showing a different concentration factor. When different concentration factors result from multiple processing studies, EPA will now use the average concentration factor to determine the expected level of concentration. In addition, EPA is examining 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 concentration factor.

In response to the NFPA petition, EPA stated it would interpret the phrase RTE food as meaning food ready for consumption ''as is'' without further preparation. For instance, EPA has determined that cottonseed oil is not RTE, while oat bran is.

B. Updated Residue Chemistry Guidelines

In a notice issued September 21, 1995 (60 FR 49150), EPA announced the availability of its updated table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry. This table, commonly referred to ''Residue Chemistry Table II'' provides a listing of all significant food and feed commodities, both raw and processed, for which residue data are collected and tolerances or FARs are established. In the latest update of this table, criteria were established for inclusion of feed items, and, based on those criteria, a number of feed items were eliminated as significant animal feeds. If a commodity is not listed in table II as a significant

food or feed, a tolerance is not necessary for pesticide residues in that commodity.

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. This notice explained EPA's interpretation of which dried commodities qualify as RACs. 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. This interpretation is consistent with EPA's current practice and therefore no commodities were reclassified as either RAC or processed as a result of the interpretation.

III. Decision Framework

In analyzing whether the 26 FARs addressed in this document should be revoked, EPA has used the following decision framework. First, EPA determined whether a section 409 FAR was necessary to prevent adulteration, given the revisions to the concentration, RTE, and RAC policies as well as to table II. If application of new policies showed no FAR was needed, this document revokes the FAR on that ground. However, if the analysis showed that a FAR is still needed, then the FAR's consistency with the Delaney clause was analyzed. Contrary to the opinion expressed in some comments on the proposed rule (see comments of American Crop Protection Association, and EPA's response in Unit VI of this preamble), EPA does not believe that this approach is legally required under the FFDCA. EPA has chosen this approach in its discretion.

In examining whether a FAR was needed, EPA followed a stepwise process involving a series of questions. In brief, the questions are:

1. Do processing data show that there is 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 section 408 tolerance.

2. Does use of the average of concentration factors from multiple processing studies show that there is concentration of residues during processing?

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

4. Using the HAFT, do residues in processed food exceed the section 408 tolerance?

5. If a processed food item is not eaten ''as is,'' is the dilution that occurs during preparation of RTE food sufficient to reduce pesticide residues below the section 408 tolerance? EPA will evaluate the expected residue level in RTE food containing the processed food item. If the dilution of residues resulting from RTE food preparation is greater than the concentration of residues resulting from processing (the dilution factor is greater than the concentration factor), it is likely that the residues in the finished RTE food will be less than the section 408 tolerance. In this case, no FAR would be necessary for the RTE food.

If, after consideration of the above factors, a FAR was determined to be necessary, EPA then examined whether the existing FAR for the pesticide chemical violates the Delaney clause.

IV. Analysis of the FARs

EPA originally proposed to revoke all 26 FARs on the basis that they violate the Delaney clause. EPA has since determined that under its revised concentration and RTE policies, 13 FARs are not needed to prevent adulterated food. For the 13 FARs that are needed, EPA next examined their consistency with the ''induce cancer'' standard of the Delaney clause in section IV.B. of this preamble.

A. Is a FAR needed?

Under current policy, a FAR is needed when the appropriate field trial residue value multiplied by the appropriate concentration factor significantly exceeds the section 408 tolerance in the ready to eat commodity. The extent to which EPA will allow residues in the processed food to exceed the section 408 tolerance is determined on a case by case basis, taking into account the sensitivity of the analytical method used to detect the residues. In analyzing the need for section 409 FARs, EPA has taken into account not only existing section 408 tolerances but also available residue data bearing on whether the current section 408 tolerance should be revised under existing tolerance-setting policies. EPA has received large amounts of residue data as part of the pesticide reregistration program of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Review of these data in several instances shows that the existing section 408 tolerance is set either too high or too low. Tolerance adjustments would normally be accomplished through the reregistration program.

EPA, however, sees no reason to wait until these tolerances are formally revised to determine whether the pesticide concentrates for the purpose of applying the coordination policy. EPA has decided that it should base its concentration decision upon the most recent data on residues in raw crops. If those data indicate that section 408 tolerances should be adjusted, EPA has used the adjusted section 408 tolerance level as the basis for its determination of whether a section 409 FAR is needed because the pesticide concentrates. The basis for EPA's determination that a section 408 tolerance should be adjusted is in the docket for this rulemaking.

Captan on raisins. EPA proposed to revoke FARs for captan both from pre-harvest use on grapes and direct treatment to raisins.

On January 31, 1996, EPA published notice in the Federal Register (61 FR 3401) of a petition filed by the Captan Task Force requesting revocation of the section 409 FAR for raisins. The petition claims that good manufacturing practice for producing raisins requires that the raisins are washed before they are ready-to-eat and that washing raisins substantially eliminates remaining captan residues. The petition claims that because captan residues do not concentrate in washed raisins above the established residue levels on treated grapes, the FAR should be revoked.

EPA has reviewed the public comments and reconsidered the available grape/raisin processing studies. EPA agrees that washing is standard practice in raisin production, Accordingly, EPA has determined that only those studies which involve washing the raisins reflect current processing practices. When only those data which include a washing step are used to evaluate the need for a section 409 FAR for raisins, the average concentration factor for residues of captan per se on washed raisins is less than one. Therefore, no section 409 FAR is needed for residues from pre-harvest treatment.

In regard to direct post-harvest application to grapes (drying raisins), the petition claims that the section 409 FAR is not needed because there are no registered products containing captan which include label directions for post-harvest use on raisins. EPA has reviewed all labels of products containing captan, and agrees with the petitioner that there are no labels which allow postharvest use of captan on drying grapes/raisins. Therefore, the

section 409 FAR is not needed for residues resulting from post-harvest treatment of the fruit.

Ethylene oxide on ground spices. Since ethylene oxide is directly applied to processed ground spices, the existing section 409 FAR is necessary to prevent adulterated food. EPA policies on concentration and dilution in RTE foods are not relevant to a processed commodity treated directly with a pesticide.

Mancozeb on brans of oats, barley and rye; flours of oats, barley, rye and wheat. On May 19, 1993, EPA published notice in the Federal Register (58 FR 29318) of a petition filed by the Mancozeb Task Force. This petition sought the revocation of the section 409 FAR for the flours and brans of barley, oats, rye and wheat. The petitioner argued that residues do not concentrate in the brans and flours of these grains over the section 408 RAC tolerances. EPA has reviewed the available data in accordance with the new Agency policies and made the following determinations in regard to the residues of Mancozeb on brans of oats, barley and rye, and flours of oats, barley, rye and wheat.

Oat bran. The current section 408 tolerance for mancozeb on oat grain is 5 ppm (40 CFR 180.176). Evaluation of new residue data indicates that the tolerance should be reduced to 1 ppm. Based on the HAFT of 0.98 ppm for oat grain and an average concentration factor of 2.0 in oat bran, the expected residue in oat bran is calculated as 2.0 ppm. The HAFT multiplied by the concentration factor is 0.98 X 2.0=2.0 ppm. (This calculation is used throughout the document to calculate expected residue levels.) EPA believes that it is likely that some oat bran will contain residues exceeding the adjusted RAC tolerance level of 1 ppm. Oat bran is a RTE processed food and needs a section 409 FAR.

Barley and rye bran. The current section 408 tolerance for mancozeb on barley and rye grains are 5 ppm (40 CFR 180.176). Evaluation of new residue data indicate that this tolerance should be reduced to 1 ppm. Based on the HAFT of 0.98 ppm for barley and rye grain and an average concentration factor of 2.0 in the brans, the expected residues in barley and rye brans are calculated as 2.0 ppm. EPA has determined that both rye and barley bran are not RTE foods and that once they are prepared to their RTE forms, mancozeb residues are unlikely to exceed the adjusted section 408 tolerances of 1 ppm for rye and barley grains. Therefore, the section 409 FARs for mancozeb on brans of barley and rye are not needed and will be revoked on these grounds. EPA will propose to establish a Maximum Residue Limit (MRL) under section 701 of FFDCA in or on barley bran. Moreover, EPA has determined that rye bran is not a significant human food and does not require pesticide residue tolerances. A memo to this effect is in OPP docket 300415.

Flours of oat, barley, rye and wheat. The current FAR for flours of oat, barley, rye and wheat is 1 ppm (40 CFR 185.6300). EPA has determined that the average concentration factor for wheat flour is less than one, and has used it for other grains. Residues in processed flours are not expected to exceed the adjusted RAC tolerance of 1 ppm for the grains. Therefore, no section 409 FAR is needed for the flours of oat, barely, rye and wheat.

Oxyfluorfen on spearmint, peppermint, soybean and cottonseed oils. On December 14, 1994, EPA published notice in the Federal Register (59 FR 64405) of a petition filed by the Rohm and Haas Company which sought to revoke these section 409 FARs because they are not needed. The petitioner claimed that all processed oil data from processing studies show that residue levels in oils are below the section 408 tolerance levels. The petitioner also argued that these oils are not RTE commodities.

Spearmint and peppermint oils. The current section 408 tolerance for oxyfluorfen on mint hay is 0.1 ppm (40 CFR 180.381). Evaluation of new residue data indicates that the tolerance should be reduced to 0.05 ppm. Based on the HAFT of 0.03 ppm for mint hay, and an average concentration factor of 2.4, the expected residues in mint oils are calculated as 0.072 ppm. The residue level for mint oils is not appreciably higher than the adjusted mint RAC tolerance of 0.05 ppm, taking into account the sensitivity of the analytical method used to detect oxyfluorfen residues. In addition, peppermint and spearmint oils are not RTE commodities, and the Agency has determined that they are diluted by a factor of 120 and 160 respectively in RTE foods. Therefore, a section 409 FAR is not needed. EPA will propose to establish Maximum Residue Limits under section 701 of FFDCA for oxyfluorfen in or on mint oils.

Soybean oil. Dry soybean seeds treated at 5 times the maximum application rate did not have quantifiable oxyfluorfen residues, thus processing data are not able to show the degree of concentration in soybean oil. The maximum theoretical concentration factor for soybean oil is 5. Since this is the same as the application exaggeration in the residue study, oxyfluorfen residues in soybean oil, are not expected to exceed the section 408 tolerance of .05 ppm. Therefore, a section 409 FAR is not needed.

Cottonseed oil. The current section 408 tolerance for oxyfluorfen on cottonseed is 0.05 ppm (40 CFR 180.381). Evaluation of new residue data indicates that the tolerance should be reduced to .02 ppm. Based on the HAFT of 0.01 ppm for cottonseed and a concentration factor of 3.3, the expected residue in cottonseed oil is .04 ppm. Cottonseed oil is not a RTE processed food and once diluted by a factor of 11, which accounts for the minimum level of dilution of cottonseed oil in preparing RTE food, the residues in the RTE food items are not expected to exceed the adjusted section 408 RAC tolerance of .02 ppm. Therefore a section 409 FAR is not needed. EPA will propose to establish Maximum Residue Limits under section 701 of FFDCA for oxyfluorfen in or on cottonseed oil.

Propargite on raisins, dried figs, and tea. On September 7, 1994, EPA published a notice in the Federal Register (59 FR 46250) of a petition filed by Uniroyal Chemical Company which sought to revoke the section 409 FAR on raisins because it is not needed. The petitioner claimed that propargite residues are susceptible to release through mechanical or washing processes and therefore do not concentrate in raisins.

Raisins. Based on the HAFT of 4.7 ppm for grapes and an average concentration factor of 1.7, the expected residue in raisins is calculated at 8.0 ppm, which is less than the established section 408 RAC tolerance of 10 ppm for grapes. Therefore, a section 409 FAR is not needed for raisins.

Dried figs. Based on a HAFT of 1.8 ppm for figs and an average concentration factor of 2.7 for dried figs, the expected residue level in dried figs is 4.9 ppm. EPA believes that it is likely that some dried figs will contain propargite residues exceeding the established RAC tolerance level of 3 ppm. Since dried figs are RTE, a section 409 FAR is needed.

Dried tea. Tea is a processed food item even though it is not considered a RTE food. EPA has determined that the degree of dilution from dried tea to brewed RTE tea will exceed any concentration from fresh green tea to dried tea.

Under the circumstances where: (1) There is a section 408 tolerance for the RAC; and (2) residues in the RTE food are below the section 408 tolerance, EPA normally would determine that the

section 409 FAR is not necessary. Residues would be covered by the section 408 tolerance under the flow-through provision of section 402, and EPA would revoke the FAR on that ground.

Tea presents a unique situation, because the FAR is established primarily for import purposes. However, because only the dried tea is imported into the United States, there is no section 408 tolerance for fresh tea. Without a section 408 tolerance, the flow-through provision does not apply. Revocation of the section 409 FAR would leave no tolerance to cover residues in tea, potentially resulting in adulterated tea. Therefore, the section 409 FAR for dried tea is necessary.

Propylene oxide on glace fruit, cocoa, gums, dried prunes, processed nutmeats (except peanuts), starch and processed spices. Since propylene oxide is directly applied to these commodities, the ''flow through'' provision of section 402 does not apply and the existing section 409 FAR is necessary to prevent adulterated food.

Simazine on Sugarcane molasses and syrup. Molasses is a RTE food item. The average concentration factor in the processing of molasses is 10. A determination of the HAFT has not been made since the concentration factor is so large that the HAFT multiplied by that number is certain to appreciably exceed the section 408 tolerance (.25 ppm). EPA expects that in most cases the HAFT will not be lower than the tolerance by a factor of two. This conclusion is based on EPA's experience with setting 408 tolerances (i.e., how they are derived based on the highest residue values) and with the relationships between average residues in field trials and either tolerances or maximum field trial residues, which are usually close to the tolerance. In most cases average residues across all field trials for a given crop are 2–6 times less than a tolerance or maximum field trial value. The highest average field trial (HAFT) will be higher than the average residue across all trials. Therefore, in this particular case the Agency is confident that ten times the HAFT will be appreciably higher than the 408 tolerance. Examples of the relationships between average residues and tolerances or maximum field trial residues are available in the docket for this notice. EPA's conclusion regarding the level of simazine residues in sugarcane molasses is confirmed by a processing study in which sugarcane treated at the maximum application rate showed total residues of 0.63 ppm in molasses, well above the 0.25 ppm sugarcane tolerance. Therefore, EPA believes that it is likely that some molasses will contain residues exceeding the tolerance.

According to Residue Chemistry Table II, sugarcane syrup is not considered a significant human food item. The Agency has determined that no section 409 FAR is required.

Simazine in potable water. Even though EPA no longer sets section 409 FARs under the FFDCA for residues in potable water, this FAR for simazine exists. Therefore, EPA will apply the same analysis to it as to the other section 409 FARs addressed in this notice.

B. Induce Cancer Determination

If a FAR is necessary to prevent adulterated food, as in the case of the 13 FARs of the five chemicals discussed above, EPA must determine whether the pesticide induces cancer within the meaning of the Delaney clause. In the proposal for this final rule (59 FR 33941; July 1, 1994), EPA determined that all of the following five chemicals ''induce cancer'' within the meaning of the Delaney clause: Ethylene oxide, mancozeb, propargite, propylene oxide and simazine. (OPP docket 300335.)

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 5 chemicals addressed above. Based on this analysis, EPA concludes that ethylene oxide, mancozeb, propargite, propylene oxide and simazine induce cancer within the meaning of the Delaney clause. Because EPA has determined that the section 409 FARs for captan and oxyfluorfen should be revoked on grounds other than the Delaney clause, the Agency is not issuing a final finding in this action that these chemicals induce cancer within the meaning of the Delaney clause. Full copies of EPA's reviews of each chemical and other references in this document are available in the OPP docket 300335, the location of which is given in the ''ADDRESSES'' section of this preamble.

V. EPA's Decisions

A. FARs That Are Not Needed

Captan. EPA is revoking the FAR for the fungicide captan in or on raisins (50 ppm). This FAR is codified at 40 CFR 185.500. EPA is revoking this regulation because the Agency has determined that this FAR is not needed to prevent adulterated food. This final rule is based on the grounds discussed in the petition of January 31, 1996, discussed in Unit IV of this preamble.

Mancozeb. EPA is revoking the FARs for mancozeb (expressed as the zinc ion and maneb coordination product) for residues in the brans of barley and rye (20 ppm) and in the flours of barley, oats, rye and wheat (1 ppm). These FARs are codified at 40 CFR 185.6300. EPA is revoking these FARs because they are not needed to prevent adulterated food. This final rule is based on the grounds discussed in the petition of May 19, 1993, discussed in Unit IV of this preamble.

Oxyfluorfen. EPA is revoking the FARs for residues of oxyfluorfen on cottonseed oil, peppermint oil, spearmint oil and soybean oil (.25 ppm). These FARs are codified at 40 CFR 185.4600. EPA is revoking these FARs because the Agency has determined that these FARs are not needed to prevent adulterated foods. This final rule is based on the grounds discussed in the petition of December 14, 1994, discussed in Unit IV of this preamble.

Propargite. EPA is revoking the FAR for residues of propargite on raisins (25 ppm). This FAR is codified at 40 CFR 185.5000. EPA is revoking this FAR because the Agency has determined that it is not needed to prevent adulterated food. This final rule is based on the grounds discussed in the petition of September 7, 1994, discussed in Unit IV of this preamble.

Simazine. EPA is revoking the FAR for residues of simazine in sugarcane syrup (1 ppm). This FAR is codified at 40 CFR 185.5350. EPA is revoking this FAR because EPA has determined that it is not needed to prevent adulterated food. This final rule is based on updated Agency guidelines which dictate when a FAR is needed.

TABLE 1.—13 FARS THAT ARE NOT NEEDED

Pesticide	CFR citation	Commodity	Food additive regulation level
Captan	185.500	raisins	50.0 ppm
Mancozeb	185.6300	bran of barley, rye	20 ppm
		flours of oats, barley, rye, wheat	1 ppm
Oxyfluorfen	185.4600	peppermint, spearmint, soybean, and cottonseed oils	0.25 ppm
Propargite	185.5000	raisins	25 ppm
Simazine	185.5350	sugarcane syrup	1 ppm

B. Food Additive Regulations That Violate the Delaney Clause

Ethylene oxide. EPA is revoking the FAR for residues resulting from the direct application of ethylene oxide to ground spices (50 ppm). This FAR is codified at 40 CFR 185.2850. Ethylene oxide has been found to induce cancer in animals based on tests which are appropriate for the evaluation of the safety of food additives. Thus, this regulation violates the Delaney clause in section 409 of the FFDCA.

Mancozeb. EPA is revoking the FAR for mancozeb (expressed as the zinc ion and maneb coordination product) for residues in oat bran (20 ppm). This FAR is codified at 40 CFR 185.6300. Since mancozeb induces cancer when ingested by animals, this regulation violates the Delaney clause in section 409 of the FFDCA.

Propargite. EPA is revoking the FARs for residues of propargite on dried figs (9 ppm) and dried tea (10 ppm). These FARs are codified at 40 CFR 185.5000. Since propargite induces cancer when ingested by animals, these regulations violate the Delaney clause in section 409 of the FFDCA.

Propylene oxide. EPA is revoking the FARs for residues of propylene oxide on cocoa (300 ppm), glace fruit (700 ppm), gums (300 ppm), processed nutmeats (except peanuts) (300 ppm), dried prunes (700 ppm), processed spices (300 ppm), and starch (300 ppm). These FARs are codified at 40 CFR 185.5150. Since propylene oxide induces cancer in animals in tests appropriate for the evaluation of the safety of food additives, these regulations violate the Delaney clause in section 409 of the FFDCA.

Simazine. EPA is revoking the FARs for residues of simazine on sugarcane molasses (1 ppm) and in potable water (.01 ppm). These FARs are codified at 40 CFR 185.5350. Since simazine induces cancer when ingested by animals, these FARs violate the Delaney clause in section 409 of the FFDCA.

TABLE 2.—13 FARS THAT VIOLATE THE DELANEY CLAUSE

Pesticide	CFR citation	Commodity	Food additive regulation level
Ethylene oxide	185.2850	ground spices	50 ppm
Mancozeb	185.6300	bran of oats	20 ppm
Propargite	185.5000	dried figs	9 ppm
		dried tea	10 ppm
Propylene oxide	185.5150	glace fruit	700 ppm
		cocoa	300 ppm
		gums	300 ppm
		processed nutmeats (except peanuts)	300 ppm
		dried prunes	700 ppm
		starch	300 ppm
		processed spices	300 ppm
Simazine	185.5350	sugarcane molasses	1 ppm
		potable water	.01 ppm

VI. Consideration of Comments

EPA's proposed revocation of these FARs was published prior to EPA's response to the NFPA petition. Many comments that were submitted in response to the proposed rule urged EPA to reconsider many of its tolerance setting policies, including the coordination, concentration, RTE and RAC policies. As explained in the earlier units of this notice, EPA has adopted new policies and used them in making the determinations for this final rule. Because of these new policies, only 13 of the 26 FARs which EPA proposed to revoke on July 1, 1994, are being revoked because they violate the Delaney clause. In addition, most commenters also raised chemical specific issues, primarily concerning whether the chemical induces cancer within the meaning of the Delaney clause. EPA's response to chemical specific comments is summarized below. Full responses to comments are in the docket.

American Crop Protection Association (ACPA)

Comments: ACPA submitted extensive comments on the proposal.

Many of ACPA's comments seem to suggest that EPA has incorrectly applied the legal standard ''induce cancer'' because EPA failed to duplicate prior FDA practice. ACPA admits that EPA announced it would use FDA's ''induce cancer'' standard and would follow the weight of the evidence approach used by FDA but ACPA contends that EPA's application of the standard was not sufficiently thorough and that EPA has failed to consider various categories of relevant evidence. ACPA alleges that one particular type of evidence ignored by EPA is biologic and mechanistic data. Further, ACPA argues that EPA has wrongly interpreted the Delaney clause because EPA has failed to take into account the relevance of the results of animal studies to humans. ACPA also asserts that EPA failed to take account of the fact that an ''induce cancer'' finding is appropriate only where the evidence is ''conclusive.'' Finally, ACPA argues that EPA is legally required to determine whether a section 409 FAR is legally necessary to prevent the adulteration of food before revoking it on Delaney clause grounds.

EPA's response: EPA believes its application of the ''induce cancer'' standard and the weight of the evidence approach has sufficiently addressed all relevant evidence. Where ACPA or other 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. ACPA's comments regarding the role of the relevance of animal studies to humans under the Delaney clause, the relevance of biologic and mechanistic data, the degree of certainty required for a Delaney clause finding, and the need for a determination as to the necessity of a FAR are addressed below.

Relevance to humans. ACPA asserts that a substance does not induce cancer within the meaning of the Delaney clause even if it produces cancer when fed to experimental animals if the results of the experiment are not relevant to human carcinogenicity. To support this conclusion, ACPA first notes that the Delaney clause contains two clauses separated by the conjunction ''or.''

> [N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man *or* animal or 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 * * *.

21 U.S.C. 348(c)(3)(A) (emphasis added). According to ACPA, the first clause is limited to evidence gathered through epidemiological studies on humans or animals and the second clause addresses evidence gathered from experiments. ACPA bases this conclusion on the inclusion of the word ''tests'' in the second clause but not in the first. Further, ACPA argues that the requirement that the tests be ''appropriate for the evaluation of the safety of food additives'' mandates that EPA must consider the relevance of both the test design and the test results to human carcinogenicity. For example, ACPA asserts that if the test produces cancer in the animals but that cancer would not be produced in humans then the substance does not induce cancer in animals under the Delaney clause because the test was inappropriate for an evaluation of human carcinogenicity. A failure to consider the relevance of test results to humans, ACPA contends, would make the focus of the Delaney clause protection of the health of experimental animals, not humans.

EPA disagrees with each step of ACPA's analysis. First, EPA believes that the feeding studies with experimental animals fall within the first clause of the Delaney clause. It is a difficult stretch to suggest that a substance that has produced cancer in an animal feeding study has not been ''found to induce cancer when ingested by * * * animal[s].'' This is especially the case when the alternative interpretation is that this phrase refers to a type of study—an epidemiological study of animals—which is rarely if ever used to evaluate carcinogenicity.

Moreover, the legislative history refutes ACPA's proposed interpretation. The second half of the Delaney clause concerning appropriate tests was included in the anti-cancer provision because of a concern that tests other than feeding studies might be deemed controlling under the Delaney clause. At the same time the ''appropriate'' tests clause was added, the original clause was amended to add a reference to ingestion, thus signaling a special status for ingestion studies.

Congressman Delaney's anti-cancer clause as initially drafted stated: ''The Secretary shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals.'' H.R. 7798, 85th Cong., 1st Sess., section 409 (d), reprinted in XIV A Legislative History of the Federal Food, Drug, and Cosmetic Act at 97 [hereinafter cited as Leg. Hist.]. At first, the Department of Health, Education and Welfare (HEW) objected to a specific mention of cancer in the Food Additive Amendments but relented and proposed the anti-cancer language which was enacted. HEW explained in detail the reason for revising the initial anti-cancer clause:

> It would be important, also to use language that would provide the intended safeguards without creating unintended and unnecessary complications. For example, the language suggested by some to bar carcinogenic additives would, if read literally, forbid the approval for use in food of any substance that causes any type of cancer in any test animal by any route of administration. This could lead to undesirable results which obviously were not intended by those who suggested the language. Concentrated sugar solution, lard, certain edible vegetable oils, and even cold water have been reported to cause a type of cancer at the site of injection when injected repeatedly by hypodermic needle into the same spot in a test animal. But scientists have not suggested that these same substances cause cancer when swallowed by mouth.
>
> The enactment of a law which would seem to bar such common materials from the diet would place the agency that administered it in an untenable position. The agency would either have to try to enforce the law literally so as to keep these items out of the diet—evidently an impossible task—or it would have to read between the lines of the law an intent which would make the law workable, without a clear guide from Congress as to what was meant.
>
> This difficulty could readily be avoided, if there is still a desire to make specific mention of cancer in the bill, by providing that ''no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate to the evaluation of the safety of food additives, to induce cancer in animals.''

104 Cong. Rec. 17415 (1958), XIV Leg. Hist. at 869 (reprinting a letter from Elliot L. Richardson, Assistant Secretary, Department of HEW). If HEW had intended that HEW be granted discretion to decide whether any test was appropriate for evaluating the safety of food additives, even ingestion studies, the word ''appropriate'' could have simply been inserted before ''tests'' in Congressman Delaney's draft. However, the proposed revision not only added language modifying the word ''test'' but rewrote the opening language of the anticancer provision by inserting a reference to ingestion and animals. This creates the clear inference that the appropriateness of ingestion studies was not open to question.

This was certainly the contemporaneous interpretation of the Delaney clause. In 1960, when the addition of a Delaney clause to the Color Additive Amendments was fully debated in Congress, the House Report on the Amendments described the Delaney clause as follows:

> This clause provides that a color additive shall be deemed unsafe and shall not be

listed for any use which will or may result in ingestion of any part of such additive, if the additive is found to induce cancer when ingested by man or animal, or if it is found to induce cancer in man or animal by other tests, *not involving ingestion*, which are considered to be appropriate for the evaluation of the safety of additives for use in food.

H. Rep. No. 1761, 86th Cong., 2d Sess. 11 (1960), XVI Leg. Hist. at 680. Similarly, the Secretary of HEW indicated at hearings on the Color Additive Amendments that HEW interpreted the ''ingestion'' part of the Delaney clause as requiring the use of scientific tests:

The conclusion that an additive ''is found to induce cancer when ingested by man or animal'' is a scientific one. The conclusion is reached by competent scientists using widely accepted scientific testing methods and critical judgment.

Color Additives: Hearings on H.R. 7624 and S. 2197 Before the Comm. on Interstate and Foreign Commerce, 86th Cong., 2d Sess. 62 (1960), XVI Leg. Hist. at 67 (statement of HEW Secretary Flemming). Finally, that the ''ingestion'' half of the Delaney clause was interpreted as covering feeding studies and thus as being the principal operative phrase in the Delaney clause is confirmed by HEW's reaction to a proposal to delete the first half of the Delaney clause. HEW objected arguing that this change ''is obviously designed to weaken the anticancer clause and to allow room for the contention that our Department should establish tolerances to permit chemicals in food even though they had been found to induce cancer *when fed*.'' H. Rep. No. 1761, 86th Cong., 2d Sess. 83 (1960), XVI Leg. Hist. at 752 (reprinting letter to the Committee from HEW Secretary Flemming) (emphasis added). Following HEW's objections, this amendment was not further pursued.[1]

Second, even assuming for the sake of argument that feeding studies only fall within the second half of the Delaney clause, EPA still does not accept ACPA's suggestion that the ''appropriate'' tests language allows or requires EPA to consider the relevance to humans of the results of an animal study in determining whether a pesticide induces cancer in animals. Just as in the first half of the Delaney clause, the second half requires a finding of whether a substance induces cancer ''in man *or* animal.'' The appropriate tests language does not override the clear intent of the statutory ''or'' but merely insures that the tests relate to the safety of food additives. As the legislative history quoted above shows, the appropriate tests language was designed to give the government the discretion to take into account the ''route of administration'' in determining whether the substance would cause cancer when ''swallowed by mouth.'' Accordingly, EPA believes an ''appropriate'' test for the evaluation of the safety of food additives is one that yields information bearing on whether the substance will induce cancer in humans or animals when ingested. Clearly, an animal feeding study meets this criterion in all regards as to animals. Indeed, it would be strange to suggest otherwise. The very stimulus for the Delaney clause was that ''[l]aboratory experiments have shown that a number of substances when added to the diet of test animals have produced cancer.'' H. Rep. No. 1761, 86th Cong., 2d Sess. 11 (1960), XVI Leg. Hist. at 680.

Contrary to ACPA's contention, a focus on the potential of a substance to cause cancer in animals without considering the relevance of this cancer to humans does not make the goal of the Delaney clause the protection of laboratory animals. The underlying rationale of the Delaney clause is that science cannot establish for humans a safe dose of a substance that induces cancer in animals. As explained by HEW:

[The Delaney clause] allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.

H. Rep. No. 1761, 86th Cong., 2d Sess. 14 (1960), XVI Leg. Hist. at 683 (the Committee report adopted the statement of HEW Secretary Flemming). Thus, by enacting the Delaney clause, Congress concluded that barring substances based on findings in animals alone was the most practicable way to protect humans. ACPA may find this approach misguided but that does not make it not the law.

At bottom, ACPA's argument seeks to give EPA the discretion to set safe doses for substances found to induce cancer when fed to animals. That discretion, however, was removed by the Delaney clause. *Les* v. *Reilly*, 968 F.2d 985, 988 (9th Cir. 1992), cert. denied, 113 S.Ct. 1361 (1993). 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. ''[T]he agency may not, once a color [or food] additive is found to induce cancer in test animals in the conventional sense of the term, undercut the statutory consequence.'' Id. at 1122.

Mechanistic and biologic information. EPA believes that mechanistic and biologic information is 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. 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. For example, ACPA contends that if a substance induces cancer through a secondary mechanism (e.g., the substance causes the growth of urinary tract stones and the stones irritate the urinary tract causing cancer), then the substance does not induce cancer within the meaning of the Delaney clause.

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 elsewhere in this notice, EPA has decided either as a factual matter that those arguments are not adequately supported or that there exists other evidence showing cancer induction independent from any cancer produced through a secondary mechanism.

''Conclusive'' evidence of carcinogenicity. Citing a prior FDA decision involving cyclamates and the Delaney clause, ACPA has contended that findings of carcinogenicity under

[1] To the extent any statement in the notice published at 58 FR 37862 (July 14, 1993) implies that ingestion studies fall within the ''appropriate tests'' half of the Delaney clause, that implication was inadvertent and is inconsistent with the statute and with prior EPA precedent (50 FR 20373, May 15, 1985).

the Delaney clause must meet some unusually high level of certainty. Other commenters also made this argument. EPA disagrees. Neither the statute, nor FDA precedent for that matter, 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 straightforward requirement to make a finding certainly does not impose some extraordinary level of proof.

Further, EPA does not believe the FDA decision on cyclamates requires a higher standard of proof. That decision does use the word ''conclusive'' in connection with the Delaney clause, but that is a factor of FDA having classified the studies involved in that case into one of three categories: (1) Conclusive or positive; (2) inconclusive but suggestive; or (3) negative (45 FR 61474, 61481–61482, September 16, 1980). This breakdown was made so as to explicate whether the proper showing of safety could be made under the section 409 safety standard excluding the requirements of the Delaney clause. FDA concluded that inconclusive but suggestive studies would have to be addressed by a petitioner attempting to show a compound was ''safe'' (45 FR 61477). FDA described a positive study as a study which ''contains results that establish that a test substance causes cancer'' (45 FR 61481). EPA has found nothing in this precedent to suggest that any standard other than a preponderance of the evidence applies to the Delaney clause finding.

Determination on the need for section 409 FARs. ACPA as well as several other commenters argued that EPA is legally required to determine if a section 409 FAR is necessary to prevent the adulteration of food prior to revoking such a FAR on Delaney clause grounds. Where there are grounds for revocation of a section 409 FAR unconnected to safety, EPA generally would, as a policy matter, rely on those grounds to revoke the FAR prior to revoking finally under the Delaney clause. However, as EPA has recently explained in the Coordination Policy statement (61 FR 2377, January 31, 1996), EPA is under no legal obligation to subordinate the Delaney clause to other grounds in a revocation proceeding.

EtO

Comment: The American Spice Trade Association (ASTA) submitted a panel report which concluded that EtO is not likely to induce cancer in animals or humans when ingested as a residue on spices. The panel contends that it is inappropriate to conclude that EtO causes cancer through ingestion based on inhalation data. Therefore the revocation of the section 409 FAR because of the Delaney clause is inappropriate.

EPA's response: EPA has concluded that it is appropriate to use inhalation data to evaluate the safety of EtO as a food additive. This conclusion is based on the finding of multiple benign and malignant tumors distant from the site of exposure, which suggests that EtO has tumor inducing potential independent of route of administration. Inhalation exposure to EtO was associated with multiple benign and malignant tumors in F344 rats and B6C3F1 mice. EtO was also associated with tumor formation following oral gavage administration to Fischer rats and subcutaneous administration to NMRI mice. In addition, EtO is a genotoxic agent *in vivo* and *in vitro*. The large *in vivo* genetic toxicity database shows that EtO produces effects distant from the site of exposure. Genetic effects noted *in vivo* include micronuclei, sister chromatid exchange, germ cell effects (dominant lethal), and heritable translocations; these effects were associated with intravenous or intraperitoneal injection and inhalation exposure (Dellarco et al. 1990). These genetic toxicity data provide further support for the conclusion that EtO induces cancer.

Comment: ASTA had a number of comments regarding exposure. These comments claim that:

(1) EtO is unstable in the acid pH of the stomach based on *in vitro* hydrolysis data.

(2) Ingested EtO is likely to be detoxified by glutathione present in the gastric mucosa and epithelial cells.

(3) EtO exposure via ingestion of treated spices is expected to be significantly lower than levels associated with tumors in rodents.

(4) Consumers are unlikely to be exposed to EtO via consumption of treated spices based on residue persistence studies submitted to EPA. The study allegedly showed EtO levels in spices at or below the limit of quantification within 60 days.

EPA's response: The issue central to the Delaney clause is whether EtO induces cancer in man or animals when ingested or in a study which is appropriate to evaluate the safety of a food additive. EtO is associated with cancer in animals following inhalation, oral, and subcutaneous administration. As explained above, EPA has determined that these studies are appropriate for the evaluation of the safety of EtO as a food additive. No data have been submitted which would establish affirmatively that all EtO residues in food would break down or be ''detoxified'' in the stomach. Therefore, EPA does not believe that it should reconsider the determination that inhalation data are appropriate for evaluating EtO as a food additive on these grounds. Further, as explained above, EtO is associated with genetic toxicity, including heritable mutation, *in vivo* following oral, inhalation, intraperitoneal, and intravenous administration.

The level of human exposure to EtO residues in treated spices is not relevant to the Delaney clause. As stated above, the critical issue is that EtO has been found to induce cancer in animals. The Delaney clause does not allow EPA to consider exposure levels. Although residue chemistry data submitted to the Agency show that EtO residues in spices dissipate over time, the data also show that sufficient residues remain so that a tolerance is needed for spices treated with EtO.

Comment: ASTA commented that the EPA Office of Pesticide Programs (OPP) should conduct a peer review of the carcinogenicity of EtO, and should not rely on a Health Assessment Document developed by the EPA Office of Research and Development (ORD) to establish the carcinogenicity of EtO.

EPA's response: The ORD Health Assessment Document cited in the proposal for this rule is an EPA document which reflects the position of the Agency on the carcinogenicity of EtO. This document was subjected to peer review, both internal and external, prior to publication. In addition, the content of the document was independently peer-reviewed in a public session by the Environmental Health Committee of EPA's Science Advisory Board. Therefore, the Agency does not believe that additional peer review of this finding is needed at this time.

Comment: ASTA stated its position that revocation of the FAR for EtO is a *de facto* cancellation of EtO's registration under FIFRA, and that therefore due process requires that FIFRA section 6 procedures be followed in this action. ASTA also suggested that EPA refer the matter of whether EtO induces cancer to the Scientific Advisory Panel (SAP).

EPA's response: EPA has clearly stated its policy on coordination between FFDCA and FIFRA. 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. EPA does not believe that the rulemaking procedures in the FFDCA violate Constitutional due process. With respect to ASTA's suggestion that EPA consult the SAP, there is no requirement that EPA refer FFDCA tolerance revocations to the SAP prior to taking action. The Agency has reviewed all the available information on EtO and has made its determination that EtO induces cancer within the meaning of the Delaney Clause. In addition, as noted above, the EPA Health Assessment Document for EtO, which included an evaluation of the chemical's carcinogenicity, was peer-reviewed in a public session by the Environmental Health Committee of EPA's Science Advisory Board.

Comment: The National Food Processors' Association (NFPA) and Grocery Manufacturers Association (GMA) commented that EPA should withdraw the proposed section 409 revocation of EtO pending a detailed reexamination of the data.

EPA's response: EPA has made the findings in this notice with respect to EtO after reviewing all available information, and sees no reason to withdraw the proposal based on the speculation that other information might become available someday which would disprove this finding. If interested persons submit new information on the carcinogenicity of EtO in the future, EPA will review it and consider then whether additional regulatory action is warranted.

Mancozeb

Comment: The Mancozeb Task Force (MTF) objected to EPA's conclusions that exposure to mancozeb causes an increased incidence of benign and malignant thyroid tumors in rats and an increasing trend of tumors at the highest dose tested (HDT). The MTF believes that these tumors resulted from exposure to ETU formed metabolically from mancozeb.

EPA's response: The Agency is aware that ETU is a contaminant and degradation product present in mancozeb, and that ETU is a plant and animal metabolite of mancozeb which is present in food treated with mancozeb. Exposure to either mancozeb or ETU results in induction of the same tumor type (thyroid tumors) in rats (ETU also induced thyroid and liver tumors in mice). Consistent with prior FDA decisions, EPA believes that the Delaney clause applies to metabolites of a food additive as well as the parent compound. (See, e.g., 56 FR 41902, 41909, August 23, 1991.)

Comment: The MTF also argued that the rat thyroid lesions resulted from overstimulation of the thyroid and the development of proliferative lesions when the threshold for thyroid-pituitary feedback is exceeded on a chronic basis.

EPA's response: This may be a plausible mechanism for the thyroid tumors in rats. However, EPA has not received sufficient evidence to show the mechanism through which mancozeb induces cancer. Moreover, as noted in EPA's response to ACPA's comments, EPA has not determined the legal relevance of secondary mechanism claims to the Delaney clause finding.

In the Agency's Draft Policy Document on Thyroid Follicular Carcinogenesis: Mechanistic and Science Policy Considerations, SAB Review Draft, May 1988, EPA explained a mechanism through which a substance could cause thyroid cancer:

> Studies over the last several decades in multiple laboratories and using a number of different treatment regimens (e.g., iodine deficiency) have demonstrated the significance of long-term thyroid-pituitary hormonal imbalance in thyroid carcinogenesis. A consistent progression of events is noted: reduction in thyroid hormone concentrations, elevation in thyroid stimulating hormone (TSH) levels, cellular hypertrophy and hyperplasia, nodular hyperplasia, and neoplasia. Hyperplasia and sometimes neoplasia of the pituitary may also be seen * * *. A block in any of the early steps act as a block for subsequent steps including tumor development, and cessation of treatment at an early stage in the progression results in regression toward normal thyroid structure and function.

Two basic questions must be addressed before this draft policy is applied. The MTF has not submitted data establishing that the neoplasms found in the mancozeb studies are due to thyroid-pituitary imbalance, or that other carcinogenic mechanisms can be discounted. Specifically, the MTF has not submitted data to demonstrate any of the following six points:

(a) Goitrogenic activity *in vivo*;

(b) Clinical chemistry changes (e.g., reduced thyroid hormone and increased TSH serum concentrations);

(c) Specific evidence of reduced hormone synthesis (e.g., inhibited iodine uptake) or increased thyroid hormone clearance (e.g., enhanced biliary excretion);

(d) Evidence of progression (e.g., hypertrophy/hyperplasia, nodular hyperplasia–neoplasia);

(e) Reversibility of effects after exposure is terminated; and

(f) Structure Activity Relationships (SAR) to other thyroid tumorigens.

Comment: The MTF also commented that the FAR for mancozeb in or on brans and flours is not necessary because residues do not concentrate in RTE foods above the level of the RAC tolerance, and that EPA should complete action on the Task Force's petition to revoke the FAR for brans and flours on that basis.

EPA's response: As discussed above in EPA's coordination policy, EPA does not have any obligation to determine whether or not a FAR is necessary before proceeding to revoke it. However, EPA has reviewed the Task Force's petition, and, as discussed in Unit V.A. of this preamble, where EPA agrees with the petition, EPA is revoking the FAR on grounds that the residues do not concentrate above the level of the RAC tolerance. The FARs for mancozeb in or on flours of oat, barley, rye and wheat, and for brans of barley and rye are not needed, and are being revoked on that basis. EPA did not agree with the petition with respect to oat bran, which is a RTE food. Therefore, the FAR for oat bran is being revoked because it violates the Delaney clause.

Propargite

Comment: Uniroyal Chemical Co., Inc. commented that the Agency has not performed a weight of the evidence review of all available data and information on propargite, including mechanistic considerations. Uniroyal also asserted that EPA's ''induces cancer'' determination does not reflect that one mutagenic study was negative and ignores all other mutagenicity studies. Based on one negative mutagenicity study and strong evidence for a secondary mechanism for tumors in rats, Uniroyal argued that propargite cannot be said to induce cancer.

EPA's response: After a full evaluation of all the data and supporting information regarding animal carcinogenicity, EPA concludes that exposure to propargite results in an increased incidence of undifferentiated sarcoma of the jejunum in both sexes of Sprague-Dawley rats. This rare (unusual site) and malignant tumor was produced with a high incidence and is fatal. The mutagenicity data support the carcinogenicity of propargite.

The commenter argues that the jejunal tumors were caused by a secondary mechanism involving cell proliferation. In support, the commenter submitted a study purporting to show that propargite only causes cell proliferation at high doses. The theory that cancer can be caused by cell proliferation, and that proliferation is subject to a

threshold, is just that—a theory. The Agency has yet to validate the cell proliferation model as it tentatively has done with regard to the mechanism involving thyroid-pituitary hormonal imbalance in thyroid carcinogenicity (see EPA's response to secondary mechanism comment on mancozeb, above). Important basic science data are needed, like those developed for the thyroid, before EPA can even consider this model.

With respect to the comment regarding mutagenicity data, propargite was demonstrated to be mutagenic in a Chinese hamster ovary cell gene mutation study in the absence, but not presence of metabolic activation; this indicates that propargite is a direct-acting mutagen. Propargite produced positive and negative results in two replicate experiments for micronuclei in mouse bone marrow. Propargite was negative in an older, unclassified Salmonella gene mutation assay and for unscheduled DNA synthesis. Overall, these data provide evidence for mutagenicity that would support a finding of carcinogenicity.

Comment: Uniroyal also commented that revocation of the FARs for propargite may increase dietary risk to consumers and raise the cost and lower the quality of food. Finally, Uniroyal commented that raisins and dried tea should be classified as RACs rather than as processed foods.

EPA's response: The concerns raised by Uniroyal regarding relative dietary risks and cost or quality of food are not relevant to the analysis of FARs under the Delaney clause. The Delaney clause contains no provision for consideration of exposure levels, relative risks, or cost impacts. See *Les* v. *Reilly*, 968 F.2d 985 (9th Cir. 1992), *cert. denied*, 113 S.Ct. 1361 (1993).

With regard to whether raisins and dried tea are RACs or processed foods, EPA recently issued an interpretive ruling defining RACs. Under this ruling, commodities which are routinely dried for storage or transportation purposes are considered RACs, while commodities which are dried for the purpose of creating a distinct commodity are considered processed. As specifically discussed in that ruling, raisins are produced by a drying process that converts one distinct commodity (i.e. grapes) into another distinct commodity (i.e. raisins). Therefore, raisins are a processed food.

EPA has found that dried tea is also a processed food, but for a slightly different reason. Tea leaves are not only dried prior to storage and transport; some varieties constituting a significant amount, if not the majority, of tea imported into this country, are fermented to various degrees prior to drying. Fermenting is certainly within the meaning of ''processing,'' therefore the status of dried tea as a processed food was not affected by the RAC interpretation of drying. Although there are some varieties of tea which are not fermented prior to the drying process, the propargite tea FAR applies to dried tea generally, and thus must be revoked.

Propyline Oxide

Comment: The Warren Chemical Co. (Warren) commented that inhalation studies should not be used to determine carcinogenicity because propylene oxide converts to propylene glycol in the stomach.

EPA's response: The Agency believes that inhalation studies are appropriate for evaluating the safety of propylene oxide due to the appearance of tumors in both mice and rats at a site distant (e.g. in the mammary gland) from the route of exposure (inhalation). EPA does not have sufficient data to establish that ingestion of propylene oxide residues in foods would only result in exposure to propylene glycol, as the commenter asserts. Therefore, the Agency believes that the inhalation data are appropriate for the evaluation of propylene oxide.

Comment: Warren also commented that EPA's finding that female mice showed a significant dose related trend of mammary gland adenocarcinomas relative to controls did not consider a statement in the study report. The authors of the study stated that the tumor incidence was within the range found in historical untreated controls, and that they did not consider the incidence of this tumor to be related to exposure to propylene oxide.

EPA's response: For comparisons of tumor incidence in treated and control animals, it is the concurrent control which is the primary reference. The following excerpt is from EPA's ''Guidelines for Carcinogen Risk Assessment'' (51 FR 33992–34003, September 24, 1986)

> To evaluate carcinogenicity, the primary comparison is tumor response in dosed animals as compared with that in contemporary matched control animals. Historical control data are often valuable, however, and could be used along with concurrent control data in the evaluation of carcinogenicresponses.

Thus, comparisons with historical controls are secondary to those with concurrent controls. Historical control data when it is from the same laboratory and same time period as that in which the study was performed may be used to determine if the concurrent control response is within the normal range. EPA often disagrees with authors of studies regarding the significance of certain observations. In this case, the EPA review considered the concurrent controls a more appropriate reference for comparing the tumor incidence in treated animals. In any event, there were tumors found in the rat study as well, which fact also forms part of the basis for EPA's finding that propylene oxide induces cancer.

Comment: Warren also commented that EPA should not consider fibroadenomas when applying the Delaney clause because a fibroadenoma could possibly disappear without becoming malignant.

EPA's response: A fibroadenoma is a benign neoplastic lesion. Adenocarcinomas are malignant and can arise within fibroadenomas. A fibroadenoma may or may not progress to a carcinoma. As discussed above, an increase in the incidence of malignant tumors or, where appropriate, benign tumors or a combination of benign and malignant tumors, satisfy the ''induce cancer'' standard under the Delaney clause. In any event, adenocarcinomas were also found in the study where fibroadenomas occurred.

Comment: Warren also argued that EPA should not rely on the rat gavage study for each of the following reasons:

(a) It showed tumors only in the forestomach, an organ humans do not have.

(b) EPA's peer review did not take into account the fact that propylene oxide converts in the stomach to propylene glycol.

(c) The study went on for three years instead of two, which is improper because older rats are more susceptible to cancer.

(d) Human stomachs have a protective lining which rat forestomachs do not have.

(e) Gavage, or pipetting substance into an animal's stomach, is not what ''ingested'' means in the context of the Delaney clause.

EPA's response: (a) The commenter points out that humans do not have forestomachs, and argues that tumors in this organ should be disregarded by EPA in assessing the carcinogenicity of propylene oxide. However, it is not always possible to draw a direct site to site correlation between tumors in different species. Just because humans do not have forestomachs does not mean that there could not be any tumorigenic response in another organ. In any event, the absence of a forestomach in humans does not affect the fact that cancer was induced in the rat forestomach.

(b) EPA addressed the issue of conversion of propylene oxide to

propylene glycol in the stomach in its response to a prior comment above.

(c) The commenter argues that because the study lasted three years instead of two, the Q* or cancer potency factor assigned to propylene oxide should have been revised. The fact that the study lasted three years instead of two does not necessarily mean that its findings were not valid. Although older rats may tend to get more cancer than younger rats, the concurrent control animals also aged, and their chance of developing tumors increased with that of the treated animals. Whether or not the Q* should account for this element of the study is not relevant to the determination that tumors were produced in the study, and therefore propylene oxide induces cancer. An ''induces cancer'' finding under the Delaney clause does not depend on relative potency.

(d) The commenter speculates that the protective lining of the human stomach would protect it from any tumor-causing effects of exposure to propylene oxide, therefore rat forestomach tumors cannot be relevant to whether propylene oxide residues in food would cause cancer in humans. However, there is no data to support the commenter's theory that such a protective lining would have prevented the forestomach tumors in the rat study. As noted above, there is not necessarily a direct site to site correlation between species. EPA does not believe that this speculation forms any basis to disregard the rat gavage study.

(e) The Agency believes that studies where test compounds are administered to treated animals by gavage are ''ingestion'' studies within the meaning of the Delaney clause. EPA also believes that gavage studies are generally appropriate for the evaluation of the safety of food additives. See EPA's response to comments of Grocery Manufacturers' Association, below.

Comment: Finally, Warren commented that there is no alternative sterilant for cocoa or for nutmeats. The commenter noted that irradiation is not appropriate for treatment of cocoa powder because irradiated cocoa tends to turn rancid. The commenter also noted that irradiation is not a viable alternative for all spices because it degrades the oils and flavor of some spices (like chili powder). Finally, the commenter stated that irradiation would impose high costs on production of these commodities.

EPA's response: As noted earlier regarding costs of food, availability of pesticide alternatives is not relevant to the Agency's decisions on FARs under the Delaney clause. EPA can only consider whether the substance at issue induces cancer when ingested by man or animals, or when tested in a test which is appropriate for evaluating the safety of a food additive.

Comment: John A. Todhunter commented on behalf of Aberco, Inc., a registrant of pesticides containing propylene oxide. With regard to cocoa, Dr. Todhunter commented that there will be no propylene oxide residues in foods made with treated cocoa powder because the cocoa is incorporated into foods which are processed at high temperatures (i.e. baked or cooked foods). With regard to gums and spices, Dr. Todhunter commented that propylene oxide is not a pesticide under the FFDCA when it is used to sterilize gums and spices. The commenter argued that FDA has listed gums and spices as ''generally regarded as safe'' (GRAS), and that therefore anything which becomes a constituent of a GRAS substance through good manufacturing practices (GMP) cannot be regulated under section 409. The commenter cited FDA regulations at 21 CFR 182.10 (spices) and 184.1330 through 184.1351 (gums). With regard to starch, Dr. Todhunter commented that propylene oxide is not a pesticide under the FFDCA when it is used to sterilize starch because starch is not a RAC. The commenter also stated that there will be no propylene oxide residues on foods made with treated starch because the starch is later incorporated into foods and beverages which are all processed at high temperatures. Dr. Todhunter also recommended that EPA establish tolerances for propylene oxide on cocoa powder, gums and starch under section 406 of the FFDCA. Dr. Todhunter further commented that the nuts on which propylene oxide is used are not ''processed nutmeats'' but are RACs, and therefore propylene oxide should be regulated under FFDCA section 408 rather than 409.

EPA's response: EPA disagrees with most of these comments. First, propylene oxide, when used to sterilize these processed foods, is a pesticide as defined under FIFRA because it is used to destroy or mitigate pests. See 7 U.S.C. 136(u). Cocoa powder is a processed food which is treated before it moves in commerce, therefore propylene oxide is a food additive when used to treat cocoa powder. Whether residues would remain in the cocoa after it is incorporated into other foods is not relevant to whether or not a FAR is necessary for propylene oxide residues on cocoa powder.

Edible gums and spices are processed foods which are treated with propylene oxide before they move in commerce, therefore propylene oxide is a food additive when used to sterilize them. Whether or not use of propylene oxide is part of GMP for production of these foods is not relevant to whether or not a FAR is necessary for propylene oxide residues. The regulations cited are simply the FDA's listing of the gums and spices themselves as GRAS. The FDA regulations are not intended to make anything which may become part of the foods (such as a sterilant) GRAS.

Starch is a processed food which is treated before it moves in commerce, therefore propylene oxide is a food additive when used to treat starch. Whether residues would remain in a food made from treated starch after it is incorporated into other foods is not relevant to whether or not a FAR is necessary for propylene oxide residues on starch.

The notion that EPA should regulate pesticides in processed foods under FFDCA section 406 was raised by NFPA in their second petition submitted in July 1995. EPA responded to this issue in the notice issuing the Coordination Policy (61 FR 2377, January 25, 1996). To the extent that Congress left EPA with discretion to regulate pesticides under either sections 406 or 409, EPA has declined to change from its current practice.

With regard to nutmeats, EPA agrees that nutmeats per se are a RAC that should have a raw food tolerance established under FFDCA section 408. See Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry Table II (October 1982, amended September 1995).

The current FAR for propylene oxide on processed nutmeats was established more than 25 years ago. EPA determined in 1982 that nuts were a RAC, and since then, has established raw food tolerances for nuts under FFDCA section 408. Although the FAR was established for ''processed'' nutmeats, it has been viewed by the industry as covering the current use of propylene oxide on nutmeats, regardless of whether they were considered raw or processed.

EPA has not yet reviewed propylene oxide in its pesticide reregistration program, at which time the discrepancy in the tolerance situation would have been addressed routinely. In light of the strict standard of the *Les* v. *Reilly* court decision, however, EPA has focused its attention more carefully on each of the statutory provisions affecting its decisions relating to tolerances. For instance, EPA has articulated or refined its policies in a number of areas, including its concentration, ready-to-eat

and raw/processed policies, discussed in Unit II of this preamble.

EPA has received a petition from SRS International corporation, on behalf of Aberco, Inc., to establish a 408 tolerance for propylene oxide on raw nutmeats. A notice of filing of this petition was published in the Federal Register on February 1, 1996 (61 FR 3696). The Agency is currently reviewing the petition and the toxicology and residue databases for propylene oxide, and will act on the petition as soon as practicable.

Simazine

Comment: Ciba-Geigy Corp. (Ciba) commented that the results of studies relied upon by EPA for its determination that simazine induces cancer are not appropriate for evaluation of the human safety of simazine as a food additive and do not demonstrate that simazine ''induces cancer'' within the meaning of Delaney Clause. Ciba's first argument for this premise was based on the fact that no increased incidence of any tumor type was observed in male or female mice which were fed simazine.

EPA's response: EPA has found that simazine induces cancer in animals when ingested within the meaning of the Delaney clause. As such, EPA was precluded from considering relevance of this finding to humans. (See response to ACPA's comments.) In construing the ''induce cancer'' standard as to animals, EPA follows a weight-of-the-evidence approach. After a full evaluation of all the data and supporting information regarding animal carcinogenicity, EPA concluded that exposure to simazine by ingestion results in increased incidence of malignant mammary gland carcinomas and malignant pituitary gland carcinomas in female Sprague-Dawley rats. The study's tumor incidence results were statistically significant when compared with concurrent controls and exceeded the upper limit of the historical control range of the testing laboratory. The pituitary tumors were fatal with a possibly accelerated onset at both the mid- and highest dose, and the mammary tumors also contributed to the increased mortality at the highest dose. There was equivocal evidence of kidney tubule tumors (an uncommon tumor type) in both sexes. The structural analogs are strongly supportive as these compounds mostly induced malignant mammary gland tumors in Sprague-Dawley rats. There was some evidence of genotoxicity for simazine, as well as for some of the analogs.

The Agency agrees that there was no increased incidence of tumors associated with Simazine exposure in the CD-1 mouse study. However, this negative study in mice does not convince EPA that simazine did not induce cancer in the study on rats.

Comment: Ciba also argued that the mid-dose level (100 ppm) in the Sprague-Dawley rat study exceeded the Maximum Tolerated Dose (MTD), based on significant reductions in survival at this dose. Based on this argument, Ciba asserted that increased incidence of mammary gland carcinomas resulted only at doses that exceeded the MTD, i.e., the mid- and high doses.

EPA's response: The Agency is not convinced that the mid-dose in female rats exceeded the MTD, because the pituitary tumors contributed to the mortality. There were statistically significant increases in mammary gland carcinomas and in pituitary adenomas and combined adenoma/carcinoma at both the mid-and highest-doses.

The study authors reported that the pituitary tumors (adenomas and carcinomas) in female rats were considered to be fatal ''by virtue of their size and compression of the mid-brain'' and thus contributed to the decreased survivability of both the mid- and highest-dose group females. In addition, their onset was 4–15 weeks earlier in the mid- and highest-dose groups as compared to the control and low dose groups.

Comment: Ciba also commented that atrazine, a structurally similar compound, while displaying a similar oncogenic profile in S-D rats and in mice, did not induce mammary tumors in the Fisher 344 female rat.

EPA's response: Simazine is one of several s-triazine compounds used in agriculture as herbicides. It is structurally related to atrazine, cyanazine, and propazine, among others. Although atrazine did not induce mammary tumors in Fisher 344 female rats, these structural analogs provide much evidence from other studies to support EPA's finding regarding simazine. Atrazine was associated with increased mammary gland tumors (primarily malignant tumors) in female Sprague-Dawley rats; early onset of mammary tumors was also observed. Cyanazine was also associated with increased mammary gland tumors (primarily malignant tumors in female Sprague-Dawley rats.) Propazine was associated with increased mammary gland tumors (primarily benign) in female Sprague-Dawley rats. The structural analogs are strongly supportive as these compounds mostly induced malignant mammary gland tumors in Sprague-Dawley rats.

Comment: Ciba asserted that simazine is not genotoxic, although the commenter admitted that a few positive genotoxicity results have been reported in the public literature. Ciba argued that potent genotoxic oncogens usually induce mammary tumors in almost one hundred percent of animals, while mammary tumor incidence with simazine was far short of one hundred percent.

EPA's response: Simazine was found negative in the Salmonella assay for gene mutations; this is consistent with other tested s-triazines. However, it is reported that simazine is positive for gene mutations in the mouse lymphoma assay, the Drosophila sex-linked recessive lethal assay, the cell transformation assay in Syrian hamster embryo cells, and plant cytogenetic assays. Simazine is also reported negative in several other assays including yeast assays, unscheduled DNA synthesis (UDS), sister chromatid exchanges, and for aneuploidy. Overall, these data suggest a possible mutagenic action for simazine. The Agency believes that the evidence of simazine's genotoxicity provides additional support for the finding that it induces cancer.

In addition, structural analogs of simazine have shown genotoxic actions as well. For example, cyanazine has evidence of positive genotoxic activity in the mouse lymphoma assay for gene mutations and for UDS in rat hepatocytes, and propazine induces gene mutations in the cultured V79 cell assay for gene mutations.

Comment: Ciba argued that Sprague-Dawley rats have a high spontaneous background rate of mammary tumors, and that any mammary tumors induced by simazine are hormonally-mediated and therefore have a threshold. Ciba asserted that therefore simazine's carcinogenicity should be regulated qualitatively with a safety factor and not quantitatively.

EPA's response: Simazine induced increased incidence of malignant mammary gland carcinomas and malignant pituitary gland carcinomas in female Sprague-Dawley rats. Mammary tumor incidence was as high as 78%, and was outside the historical control incidence of the testing laboratory. The pituitary and mammary tumors also contributed to the observed increased mortality. There was equivocal evidence of kidney tubule tumors (an uncommon tumor type) in both sexes. The structural analogs are strongly supportive as these compounds mostly induced malignant mammary gland

tumors in Sprague-Dawley rats. There was some evidence of genotoxicity for Simazine as well as for some of the analogs.

Although a hormonal mechanistic argument for the mammary tumors was proposed by the commenter, neither the Agency nor the scientific community at large has yet developed or identified protocols which could provide data to demonstrate such a mechanism. No agreed upon experimental model has been identified, and the critical step associated with the mode of action has not been identified. As discussed with respect to cell proliferation and jejunal tumors in EPA's response to comments on propargite, important basic science data must be developed, as were developed for the thyroid mechanism, before the Agency can evaluate the validity of the claim that simazine induces cancer through a hormonal mechanism. (See also EPA's response to ACPA regarding secondary mechanisms in general.)

Other Comments

Comment: GMA commented that FDA determined in 1974 that the term ''ingestion'' in the Delaney clause does not include gavage studies, and therefore the results of a gavage study would invoke the Delaney clause only if this type of study is found to be scientifically ''appropriate'' as a model for dietary exposure. The commenter submitted an excerpt of FDA's ''Study of the Delaney Clause and Other Anti-Cancer Clauses,'' (Agriculture, Environmental and Consumer Protection Appropriations for 1975: Hearings before a Subcommittee on Appropriations, House of Representatives, 93rd Cong., 2nd Sess., part 8, 1974).

EPA's response: EPA disagrees with this comment. Gavage is merely one of several different techniques for administering a test compound to animal orally. Gavage is sometimes used instead of incorporating the substance into an animal's food because a more precise dose can be given by gavage. EPA could not find any reference, other than the report cited, where FDA stated that a gavage study must be evaluated under the ''appropriate test'' prong of the Delaney clause rather than the ''ingestion'' prong. Moreover, there is no explanation in the report as to why a gavage study should not be considered an ingestion study. In any event, it is not necessary to determine whether gavage is ingestion for purposes of this notice because EPA believes that gavage studies are generally appropriate for the evaluation of the safety of a food additive because they involve dietary exposure to the test substance, albeit by forced feeding.

VII. Procedural Matters

A. Filing of Objections and Requests for Hearings

Any person adversely affected by this final rule may file written objections to the final rule, and may include with any such objection a written request for an evidentiary hearing on the objection. Such objections must be submitted to the Hearing Clerk on or before April 22, 1996. A copy of the objections and hearing requests filed with the Hearing Clerk shall be submitted to the Office of Pesticide Programs Docket Room. Regulations applicable to objections and requests for hearings are set out at 40 CFR parts 178 and 179. Those regulations require, among other things, that objections specify with particularity the provisions of the final rule objected to, the basis for the objections, and the relief sought. Additional requirements as to the form and manner of the submission of objections are set out at 40 CFR 178.25. The Administrator will respond as set forth in 40 CFR 178.30, 178.35 and/or 178.37 to objections that are not accompanied by a request for evidentiary hearing.

A person may include with any objection a written request for an evidentiary hearing on the objection. A hearing request must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on each such issue, and a summary of any evidence relied upon by the requestor. Additional requirements as to the form and manner of submission of requests for an evidentiary hearing are set out at 40 CFR 178.27. Under 40 CFR 178.32(c), the Administrator, where appropriate, will make rulings on any issues raised by an objection if such issues must be resolved prior to determining whether a request for an evidentiary hearing should be granted. The Administrator will respond to requests for evidentiary hearings as set forth in 40 CFR 178.30, 178.32, 178.35, 178.37, and/or 179.20. Under 40 CFR 178.32(b), a request for an evidentiary hearing on an objection will be granted if the objection and request have been properly submitted and if the Administrator determines that the material submitted show:

(1) There is a genuine and substantial issue of fact for resolution at a hearing.

(2) 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.

(3) Resolution of one or more of the factual issues in the manner sought by the person requesting the hearing would be adequate to justify the action requested.

Any person wishing to comment on any objections or requests for a hearing may submit such comments to the Hearing Clerk on or before May 6, 1996.

B. Effective Date

EPA is making this final rule effective May 21, 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 April 22, 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 May 6, 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.

VIII. Regulatory Requirements

A. Executive Order 12866

EPA submitted this action to the Office of Management and Budget (OMB) for review and any changes made during that review have been documented in the public record.

EPA has estimated the following economic impacts on the affected pesticide use sites:

1. Spices

EtO may currently be used either on whole spices under its raw food tolerance (40 CFR 180.151), which are then ground (processed), or directly on ground spices under the processed food tolerance being revoked today. Sixty to eighty percent of the American spice supply is imported, and an estimated 22% of those imported spices are treated with EtO.

EPA does not have information on what portion of EtO treatments are made to whole as opposed to ground spices. If EtO were unavailable for use on all spices (both whole and ground), there would be an estimated impact of $18 million to $27 million per year in increased costs of alternative treatments and loss of some untreated product. Impacts are unlikely to be this high, because only the tolerance on ground spices is being revoked. The section 408 tolerance will remain, thus allowing continued use of EtO on whole spices. To the extent that spices are currently treated whole, a portion of the above estimated impacts will not be incurred.

Moreover, EPA believes that some portion, possibly a substantial portion, of spices currently treated in ground form can be shifted to treatment in whole form. If a change to treating them whole would cost less than substitution of alternatives, impacts would be further reduced.

Alternatives to EtO treatment are limited to irradiation treatment and heat-based technologies, both of which have practical limitations. There is currently insufficient capacity of contract irradiation facilities to handle all spices currently treated with EtO. The majority of these facilities' business comes from the sterilization of medical devices which have rigorous hygienic specifications causing most facilities to not accept spices. Current heat-based technologies have an adverse effect on the color and flavor of some spices. However these limitations are expected to be reduced over time by the industry.

Only about one percent of the total U.S. spice supply is treated with propylene oxide and its loss is not expected to cause significant economic impacts.

2. Nutmeats

Propylene oxide is used to reduce microbial contamination of raw nutmeats (except peanuts) which are to be used in other food products such as ice cream, cheese, ready-to-eat cereals, some baked goods and some confections. It is used because these foods are not processed at high enough temperatures to reduce microbial contamination to acceptable levels. There appear to be no viable alternatives to propylene oxide for nutmeats used in these foods.

The section 409 FAR being revoked today does not authorize propylene oxide residues in raw nutmeats, only processed nutmeats. At the time of proposal there was no section 408 tolerance covering use of propylene oxide on raw nutmeats. The proposed revocation of the processed nutmeat tolerance would have left no tolerance covering any use of propylene oxide on nutmeats. As a result, EPA received considerable comment on the potential economic impacts of the loss of propylene oxide.

Information on the impacts of the loss of propylene oxide for nutmeats is limited, and quantifying these impacts is complicated. U.S. nut production is nearly 1 billion pounds annually. According to commenters, about 10 to 20 percent of all nutmeats are currently treated with propylene oxide. At a value of approximately $1.60 per pound, the farm value of the 10–20% of nutmeats that are treated is $160–320 million. Commenters suggested that this 10–20 percent segment of the nutmeat industry would be a total loss if propylene oxide became unavailable for use. EPA believes that this estimate is high because it assumes that there are no alternative uses of the nuts.

Untreated nuts currently are roasted or salted or added to other foods that are processed under conditions that effectively reduce microbial contaminants to acceptable levels. EPA believes that nuts that cannot be treated with propylene oxide will not be a total loss, but will be diverted into alternative uses. EPA cannot estimate with current information how much this would reduce the overall impacts on the nutmeat industry, nor can EPA estimate the impacts on the food industries whose nut supply could be severely curtailed. EPA believes that there would be substantial incentive for the affected industries to develop alternative practices or treatments to reduce microbial contamination in raw nutmeats.

EPA has received a petition to establish a section 408 raw food tolerance for propylene oxide on nutmeats. If a section 408 tolerance is granted, propylene oxide could continue to be used on nutmeats, and there would be no impacts.

3. Cocoa

Impacts to the cocoa industry of losing the use of propylene oxide are expected to be minor or insignificant. There are no chemical alternatives to propylene oxide for use on cocoa. However, with proper handling and processing techniques cocoa powder can be safely produced without propylene oxide. The U.S. imports all of its cocoa, and generally, only that cocoa which comes from relatively unsanitary processing plants (50 percent or less) is treated with propylene oxide. Without propylene oxide, switching to markets with higher quality cocoa beans and better processing plant management techniques may cause slightly higher prices to consumers for products containing cocoa powder. In 1994, the U.S. imported over 650,000 metric tons of cocoa, valued at $1 billion.

4. Dried Tea

Insignificant impacts are expected on the dried tea industry from the loss of the propargite FAR. Propargite is not registered for use in the U.S. on dried tea and is not the miticide of choice in tea exporting countries. Dicofol is the preferred miticide on tea and its FAR currently remains in effect.

5. No impacts

No impacts are expected from revocation of the FARs for the following processed foods:

Propylene oxide is no longer registered for use on the following: Glace fruit, gums, dried prunes, and starch.

EPA no longer establishes FARs in potable water. Therefore, no impact is expected due to this FAR revocation.

For the 13 FARs that are not needed (listed in table I) the section 408 tolerances and registered uses will remain effective. Therefore, no impact is expected.

Three of the section 409 FARs being revoked today also have section 408 tolerances which were proposed for revocation in the Federal Register on March 1, 1996 (61 FR 8174). The estimated impacts from the loss of these three pesticide uses are included in that notice. These FARs are mancozeb/oat bran, propargite/dried figs, and simazine/sugarcane molasses.

B. Regulatory Flexibility Act

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

In general, regulating pesticide residues and FARs in food is indiscriminate with respect to the size of the farm or business that was the source or processor of the food. The existence or absence of FARs, and the levels at which FARs are set must logically apply to all food available to U.S. consumers. In this instance, there is unlikely to be a regulatory option that would treat small businesses differently than large businesses with respect to pesticide FARs. In any event, under the Delaney clause, the Agency is compelled to take this action without regard to the economic impacts on either large or small entities.

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. The costs associated with this action are described in the Executive Order 12866 section of this preamble.

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.

List of Subjects in 40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

Dated: March 15, 1996.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR part 185 is amended as follows:

PART 185—[AMENDED]

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

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

§ 185.500 [Removed]

2. By removing § 185.500.

§ 185.2850 [Removed]

3. By removing § 185.2850.

§ 185.4600 [Removed]

4. By removing § 185.4600.

§ 185.5000 [Amended]

5. By removing from the table in § 185.5000 the entries for ''Figs, dried'', ''Raisins'' and ''Tea, dried.''

§ 185.5150 [Removed]

6. By removing § 185.5150.

§ 185.5350 [Removed]

7. By removing § 185.5350.

§ 185.6300 [Removed]

8. By removing § 185.6300.

[FR Doc. 96–7026 Filed 3–21–96; 8:45 am]

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