

■ r. Revise the heading “Subsector 523—Financial Investments and Related Activities” to read “Subsector 523—Securities, Commodity Contracts, and Other Financial Investments and Related Activities.”

■ s. Revise the industry description of NAICS code 541612, “Human Resources and Executive Search Consulting Services,” to read “Human Resources Consulting Services.”

■ t. Remove the entry NAICS code 541710, “Research and Development in the Physical, Engineering, and Life Sciences,” and add in its place the following:

541711 .....	Research and Development in Biotechnology. <sup>11</sup>	.....	11500
541712 .....	Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology). <sup>11</sup>	.....	11500
Except, .....	Aircraft .....	.....	1,500
Except, .....	Aircraft Parts, and Auxiliary Equipment, and Aircraft Engine Parts .....	.....	1,000
Except, .....	Space Vehicles and Guided Missiles, their Propulsion Units, their Propulsion Units Parts, and their Auxiliary Equipment and Parts.	.....	1,000

■ u. Remove the entry for NAICS code 561310, “Employment Placement

Agencies,” and add in its place the following:

561311 .....	Employment Placement Agencies .....	\$6.5	.....
561312 .....	Executive Search Services .....	\$6.5	.....

■ v. Revise the industry description of NAICS code 561422, “Telemarketing Bureaus and Other Contact Centers.”

■ w. Revise the industry description of NAICS code 722212, “Cafeterias,” to read “Cafeterias, Grill Buffets, and Buffets.”

■ x. Revise the heading “Sector 81—Other Services” to read “Sector 81—Other Services (except Public Administration).”

■ y. Amend footnote 11 by removing “NAICS code 541710” and adding in its place “NAICS codes 541711 and 541712.”

Dated: August 23, 2007.

Steven C. Preston,  
Administrator.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2005-0157; FRL-8143-9]

**Propylene Oxide; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of propylene oxide and for the reaction product, propylene chlorohydrin, in or on fig; grape, raisin; and plum, prune, dried, when used as a post-harvest fumigant. This rule additionally removes all directions for use currently listed in 40 CFR 180.491. Aberco, Incorporated requested these tolerances under the

Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective August 29, 2007. Objections and requests for hearings must be received on or before October 29, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2005-0157. To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the [www.regulations.gov](http://www.regulations.gov) web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [www.regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:**

Tony Kish, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9443; e-mail address: [kish.tony@epa.gov](mailto:kish.tony@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to

certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2005-0157 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 29, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2005-0157, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to

4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## II. Petition for Tolerance

In the **Federal Register** of June 27, 2007 (72 FR 35242) (FRL-8133-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F6904) by Aberco, Incorporated, 9430 Lanham-Severn Road, Seabrook, MD 20706. The petition requested that 40 CFR 180.491 be amended by establishing a tolerance for residues of the post-harvest fumigant propylene oxide, in or on fig; grape, raisin; and plum, prune, dried at 3.0; 1.0; and 2.0; respectively parts per million (ppm); and that the directions for use currently listed in 40 CFR 180.491 under paragraphs (a)(2) and (a)(4) be deleted. The petition also identified propylene chlorohydrin as a metabolite and included an enforcement method for determination of residues of propylene oxide, propylene chlorohydrin, and propylene bromohydrin in nutmeats, cocoa, and dried spices. That notice referenced a summary of the petition prepared by Aberco, Incorporated, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

The current propylene oxide tolerances include some specific directions for use regarding fumigation frequency, duration and temperature. These directions are currently on affected labels. Because these directions are already on the label, they do not need to be duplicated as part of the tolerance. Furthermore, the propylene oxide Reregistration Eligibility Document (RED) of August 2006 found that these directions should be modified on the label to exactly match the conditions under which residue trials were conducted. Therefore, all directions in 40 CFR 180.491, paragraphs (a)(2) and (a)(4) are no longer needed and can be removed. Similarly, the use directions and other information in paragraphs (a)(1), and (a)(5) can also be removed. As noted in the petition and the RED, use of propylene oxide can result in residues of propylene oxide as well as the reaction product propylene chlorohydrin. Commodities that contain salts that are treated with propylene oxide can react with chloride ion to form the propylene chlorohydrin. Propylene oxide and propylene chlorohydrin are considered separately

as residues of concern for risk assessment and tolerance assessment. Based on the differences in physical-chemical properties and toxicological effects, propylene oxide and propylene chlorohydrin were assessed separately, and, EPA is establishing separate tolerances for these chemicals within different paragraphs of tolerance regulation for propylene oxide.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of propylene oxide in or on fig; grape, raisin; and plum, prune, dried at 3.0; 1.0; and 2.0 ppm, respectively; and in addition, for residues of the reaction product propylene chlorohydrin at 3.0; 4.0; and 2.0, ppm, respectively. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable

subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by propylene oxide and propylene chlorohydrin, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> under the docket number for this rule.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. Short-, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see: <http://www.epa.gov/oppfead1/trac/science>. <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. <http://www.epa.gov/pesticides/trac/science/aggregate.pdf>.

A summary of the toxicological endpoints for propylene oxide and propylene chlorohydrin used for human risk assessment can be found at [www.regulations.gov](http://www.regulations.gov) in the risk

assessment document "Propylene Oxide—Revised HED Risk Assessment for Reregistration Eligibility Decision Document, July 31, 2006" at Table 4.4.10 on page 49/95 in Docket ID EPA—HQ—OPP—2005—0157. This identical table can also be found in the Propylene oxide RED document at the following website address: [http://www.epa.gov/opprrd1/REDS/propylene\\_oxide\\_red.pdf](http://www.epa.gov/opprrd1/REDS/propylene_oxide_red.pdf).

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to propylene oxide and propylene chlorohydrin, EPA considered exposure under the petitioned-for tolerances as well as all existing propylene oxide tolerances in (40 CFR 180.491). EPA assessed dietary exposures from propylene oxide and propylene chlorohydrin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

In estimating acute dietary exposure for propylene oxide and propylene chlorohydrin, EPA used food consumption information from the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied upon average field trial residue data and percent crop treated information for all commodities covered by existing tolerances.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide (CSFII). As to residue levels in food, EPA relied upon average field trial residue data for propylene oxide, tolerance level residues for propylene chlorohydrin, and percent crop treated information for all commodities covered by existing propylene oxide tolerances.

iii. *Cancer.* The cancer assessment for propylene oxide incorporated new residue and percent crop treated data for nutmeats and omitted guar (edible gums) as a fumigated commodity. No cancer exposure assessment is needed for propylene chlorohydrin because the cancer data which were negative for both rats and mice, showed no cancer risk to humans.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and

the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

a. The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue;

b. The exposure estimate does not underestimate exposure for any significant subpopulation group; and

c. Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

The percent crop treated values used were as follows: Herbs, spices, and bulb vegetables at 1%; tree nuts at 2%; cocoa bean at 1.3%; and 100% for the new proposed uses — fig grape; raisin; and plum, prune, dried.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no

regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which propylene oxide may be applied in a particular area.

2. *Dietary exposure from drinking water.* For propylene oxide fumigations, residues of propylene oxide and propylene chlorohydrin from drinking water are expected to be negligible because

i. Fumigations are either in closed chambers with emission reduction technology, or in temporary/intermittent outdoor field locations (tents, tarps, rail cars, etc.) at a use rate 53 times lower than that used in closed chambers, both of which result in minimal emissions, and

ii. Due to atmospheric dilution and the physical-chemical characteristics of propylene oxide, negligible residues are expected to be able to enter soil and any nearby water. Therefore, water exposures were not included in the risk assessment.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Propylene oxide and propylene chlorohydrin are not registered for use on any residential sites. However, exposure could occur to people residing near fumigation facilities. Propylene oxide and propylene chlorohydrin emissions monitoring data necessary to quantitatively estimate exposures and risks from sterilization/fumigation facilities are unavailable. Therefore, a qualitative assessment was conducted comparing the risks associated with fugitive emissions from the use of a similar chemical, ethylene oxide, in similar commercial fumigation scenarios. With the use of required buffer zones at designated distances to be added to labels, the assessment found that propylene oxide and propylene chlorohydrin residential exposure risks are not expected to be of concern.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to propylene oxide or propylene chlorohydrin and any other substances and propylene oxide or propylene chlorohydrin do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that propylene oxide or propylene chlorohydrin have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408 of FFDCFA provides that EPA shall apply an additional ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* For propylene oxide, there is no quantitative susceptibility between the rat fetuses and the dams from the rat developmental study. The study indicated a possible qualitative susceptibility since the skeletal variations (increased litter incidence for the accessory 7th cervical rib) were observed at the same dose which produced maternal toxic effects (ie. decreased body weight gain, food consumption and food efficiency). The effects in the rat fetuses are being treated as only possible evidence of qualitative sensitivity because it is questionable as to whether an accessory 7th cervical rib, which is a developmental variation, is properly characterized as a more severe effect than decreased body weight gain. Although further analysis, including

consideration of historical control information on this effect, might resolve this question, in the absence of this analysis, EPA is taking the conservative position that this particular skeletal variation is possible evidence of qualitative sensitivity.

Susceptibility in rabbits could not be adequately ascertained due to the absence of an acceptable rabbit developmental study. In the 2-generation reproduction study, there is no evidence for quantitative or qualitative susceptibility in pups exposed to propylene oxide since no offspring effects were seen at doses which produced significant systemic toxicity in parents. The degree of concern for the possible qualitative susceptibility effects seen after *in utero* exposures in rats was low because the effects (ie. increased incidence of the 7th cervical rib) are:

i. Skeletal variations and not malformations,

ii. Were seen in the presence of maternal toxicity,

iii. A clear NOAEL was identified, and

iv. This endpoint is used for assessing potential acute dietary risk to the population of concern (Females 13-49). For propylene chlorohydrin, in the reproduction study, quantitative susceptibility effects were evident because decreased pup weights were observed at a dose which had no systemic toxicity in the dams. However, the degree of concern is low for the quantitative susceptibility seen in the reproduction study because a clear NOAEL was identified, and that dose and the endpoint of this study is used for assessing chronic dietary risk in conjunction with the retaining of a 10X database uncertainty factor.

3. *Conclusion.* For both propylene oxide and propylene chlorohydrin, EPA has determined it is necessary to retain the additional 10X safety factor for the protection of infants and children due to the absence of a propylene oxide developmental toxicity study in rabbits, and a chronic study in non-rodents by the oral route; and for propylene chlorohydrin, due to the absence of a developmental toxicity study in rats and rabbits, a chronic toxicity study in nonrodents, and a chronic carcinogenicity study in rats and mice (because the doses used in the existing studies found in the literature are inadequate). Because no acute endpoint has been identified for propylene chlorohydrin, EPA has applied the additional 10X safety factor to the chronic endpoint in assessing acute risk for propylene chlorohydrin. This is a very conservative approach to assessing

acute risk because repeated exposure to a pesticide would typically result in lower NOAELs than an acute exposure. For propylene oxide, there is no evidence for quantitative or qualitative susceptibility in pups exposed to the chemical. For propylene chlorohydrin, the degree of concern is also low for the quantitative susceptibility seen in the reproduction study since the dose and the endpoint of this study is used for assessing chronic dietary risk in conjunction with the retaining of the 10X database uncertainty factor. No additional FQPA factor above 10X is required for either propylene oxide or propylene chlorohydrin. Propylene oxide is missing an adequate rabbit developmental study and a chronic study in a non-rodent species, but an existing developmental study in rabbits indicates effects occur at high doses and a chronic study in rodents is available, therefore a factor of 10X is sufficient. For propylene chlorohydrin, although there are data gaps, there are acceptable longer term studies including chronic studies in rats and mice and a reproduction study in rats. Given these chronic data, an additional safety factor of 10X should be sufficient for the protection of infants and children, as well as the general population and other major identifiable subgroups, from chronic exposure to propylene chlorohydrin. Further, use of the chronic endpoint and the additional 10X safety factor to assess acute risk is such a conservative approach to assessing acute risk that no further safety factor for this risk assessment. Other relevant factors here are that:

- i. There is no indication that propylene oxide or propylene chlorohydrin are neurotoxic chemicals and there is no need for developmental neurotoxicity studies or additional uncertainty factors to account for neurotoxicity; and
- ii. The exposure databases is unlikely to underestimate exposure because it is based on reliable data on anticipated residues and percent crop treated information.

#### E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the

MOE called for by the product of all applicable uncertainty/safety factors is not exceeded. As discussed prior, because propylene oxide and propylene chlorohydrin residues which could enter water are expected to be negligible, water exposures were not included in the aggregate risk assessments.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from only food to propylene oxide will occupy 7% of the aPAD for the population group (females 13-49 years old) receiving the greatest exposure. Because no acute endpoint has been identified for propylene chlorohydrin, EPA has assessed acute risk for propylene chlorohydrin using the cPAD for propylene chlorohydrin. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from only food to propylene chlorohydrin will occupy 90% of the cPAD for the population group receiving the greatest exposure (infants less than one year old).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to propylene oxide from only food will utilize 14% of the cPAD for the population group (children 3-5 years). Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to propylene chlorohydrin from only food will utilize 29% of the cPAD for the population group (children 1-2 years). There are no residential uses for propylene oxide or propylene chlorohydrin, but residential bystanders may be exposed to air emissions from fumigation facilities or structures. However, dietary and bystander exposure for either propylene oxide or propylene chlorohydrin cannot be combined for this assessment because the endpoints selected for these exposures are not based on a common effect. Therefore, risk from dietary and inhalation routes were not aggregated.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Though residential exposure could occur with the use of propylene oxide, the potential short-term exposures to propylene oxide and propylene chlorohydrin were not aggregated with chronic dietary food and water exposures for the same because the toxic effects are different.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure

takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Though residential exposure could occur with the use of propylene oxide, the potential intermediate-term exposures propylene oxide and propylene chlorohydrin were not aggregated with chronic dietary food and water exposures for the same because the toxic effects are different.

5. *Aggregate cancer risk for U.S. population.* The cancer dietary risk estimates for propylene oxide are below EPA's level of concern; the cancer dietary excess lifetime risk estimate for the U.S. general population is  $4 \times 10^{-7}$ . EPA considers risks in the range of  $1 \times 10^{-6}$  (such as the cancer risk for propylene oxide) to be negligible and thus pose a reasonable certainty of no harm. There is no cancer risk for propylene chlorohydrin as evidenced by the cancer data which were negative for both rats and mice.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to propylene oxide and propylene chlorohydrin residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. An acceptable method was submitted (ABC.METHOD 46306-PPO/Hydrins Rev 1.0; MRID 45301902) which is able to quantify propylene oxide and propylene chlorohydrin residues in various commodities using headspace gas chromatography with flame ionization detection. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

There are no Codex Maximum Residue Levels (MRLs) for residues of propylene oxide and propylene chlorohydrin in any commodity. No Canadian or Mexican MRLs have been established.

#### V. Conclusion

Therefore, tolerances are established for residues of propylene oxide when used as a post harvest fumigant, in or on fig; grape, raisin; and plum, prune, dried, at 3.0; 1.0; and 2.0; respectively

ppm, and separate tolerances are established for the reaction product, propylene chlorohydrin, in or on fig; grape, raisin; and plum, prune, dried, at 3.0, 4.0, and 2.0 ppm, respectively. The use directions currently listed in 40 CFR 180.491 paragraphs (a)(1), (a)(2), (a)(4) and (a)(5) are also being removed.

**VI. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10,

1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: August 17, 2007.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—AMENDED**

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

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.491 is amended by revising paragraph (a) to read as follows:

**§ 180.491 Propylene oxide; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of propylene oxide when used as a postharvest fumigant in or on the following food commodities:

Commodity	Parts per million
Cocoa bean, bean .....	300
Fig .....	3.0
Grape, raisin .....	1.0
Gum, edible .....	300
Nutmeat, processed, except peanuts .....	300
Plum, prune, dried .....	2.0
Spices, processed .....	300

(2) Tolerances are established for the reaction product, propylene chlorohydrin, from use of propylene oxide as a postharvest fumigant, in or on the following food commodities:

Commodity	Parts per million
Fig .....	3.0
Grape, raisin .....	4.0
Plum, prune, dried .....	2.0

\* \* \* \* \*

[FR Doc. E7-17010 Filed 8-28-07; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0349; FRL-8142-1]

**Spinosad; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of spinosad in or on fish; fish-shellfish, mollusc; and fish-shellfish, crustacean. Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective August 29, 2007. Objections and requests for hearings must be received on or before October 29, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0349. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in