

FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use “voluntary consensus standards” (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today’s action does not require the public to perform activities conducive to the use of VCS. This action merely determines that the Imperial County area has not attained by the applicable attainment date, reclassifies the Imperial County area as a moderate ozone nonattainment area, and adjusts applicable deadlines. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2). This rule will be effective March 14, 2008.

K. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 14, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it

extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Incorporation by reference.

Authority: 42 U.S.C. 7401 et seq.

Dated: January 24, 2008.

Jane Diamond,

Acting Regional Administrator, Region IX.

■ Part 81 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 81—[AMENDED]

■ 1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

■ 2. In § 81.305 the “California-Ozone (8-Hour Standard)” table is amended by revising the entry for “Imperial County:” to read as follows:

§ 81.305 California.

CALIFORNIA-OZONE

[8-hour standard]

Designated area	Designation		Classification	
	Date ¹	Type	Date	Classification
Imperial County, CA: Imperial County	Nonattainment	3/14/08	Subpart 2/Moderate.

¹ This date is June 15, 2004, unless otherwise noted.

[FR Doc. E8–2698 Filed 2–12–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0637; FRL–8345–1]

1,3-Dichloropropene and metabolites; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of 1,3-dichloropropene and metabolites in or on grape. Dow AgroSciences, LLC

requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 13, 2008. Objections and requests for hearings must be received on or before April 14, 2008, 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–2007–0637. 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](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [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:

Mary L. Waller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9354; e-mail address: waller.mary@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 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-2007-0637 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 April 14, 2008.

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-2007-0637, 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 September 19, 2007 (72 FR 53575-53577) (FRL-8144-3), 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 1F6253) by Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The

petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide, 1,3-dichloropropene, in or on grape at 0.009 parts per million (ppm). That notice referenced a summary of the petition prepared by Dow AgroScience, LLC, the registrant, which is available to the public in the docket, at <http://www.regulations.gov>. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has revised and raised the tolerance level to include the combined residues of the parent chemical, *cis*- and *trans*-1,3 dichloropropene, and the metabolites, *cis*- and *trans*-3-chloroacrylic acid and *cis*- and *trans*-3-chloroallyl alcohol which are considered to be of equal toxicity to the parent chemical.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of 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 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 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 FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA 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 the combined residues of *cis*- and *trans*-1,3-dichloropropene, *cis*- and *trans*-3-chloroacrylic acid, and *cis*- and *trans*-3-chloroallyl alcohol (1,3-dichloropropene and metabolites) on grape at 0.018 ppm. 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.

The toxicology database is considered to be adequate to support the proposed and existing uses of 1,3-dichloropropene. 1,3-Dichloropropene showed moderate acute toxicity by the oral and dermal exposure routes (Toxicity Category II), was moderately irritating to the eye and skin, and was a dermal sensitizer in guinea pigs. It is classified as Toxicity Category IV for acute inhalation toxicity and produced tremors, convulsions, salivation, lacrimation, diarrhea, lethargy and death at concentrations 647 ppm or higher.

Consistent with the irritant properties of 1,3-dichloropropene, there was evidence of degenerative changes in the nasal olfactory epithelium and histopathological changes of the respiratory epithelium in rats and mice after subchronic inhalation exposure. Following chronic inhalation exposure, the olfactory region of the nasal cavity appeared to be the target organ in rats while lung adenomas were induced in mice. Similarly, following oral exposure, 1,3-dichloropropene induced histopathological lesions in rats and/or mice including forestomach squamous cell papillomas and carcinomas, liver masses/neoplastic nodules, urinary bladder carcinomas, and alveolar/brochiolaradenomas. Increases in hematopoietic activity and decreased body weights were also noted in dogs and mice, respectively. Accordingly, 1,3-dichloropropene has been classified as "likely to be carcinogenic to humans" via both the oral and inhalation routes. As a result, cancer potency factors (Q1*) have been calculated for both routes of exposure.

Specific information on the studies received and the nature of the adverse effects caused by 1,3-dichloropropene and metabolites 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>. The risk assessment dated January 24, 2008 is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2007-0637 in that docket.

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 (UFs) 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 UFs. 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 UFs 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for 1,3-dichloropropene and metabolites used for human risk assessment can be found at <http://www.regulations.gov> in the document titled 1,3-Dichloropropene: Proposed New Use for Drip Irrigation in Vineyards: HED Human Health Risk Assessment at page 21 in docket ID number EPA-HQ-OPP-2007-0637.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 1,3-dichloropropene and metabolites, EPA considered exposure under the petitioned-for tolerance. There are no other tolerances for 1,3-dichloropropene and metabolites. EPA assessed dietary exposures from 1,3-

dichloropropene and metabolites 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.

No such effects were identified in the toxicological studies for 1,3-dichloropropene and metabolites; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996, or 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied upon anticipated residues and assumed 100 percent crop treated (PCT). Residues of *cis*- and *trans*-1,3-dichloropropene and three of the four metabolites were assumed to be at one-half the limit of detection (0.001 ppm) since residues were non-detectable in all field trials at shorter pre-harvest intervals (PHI) than the proposed use pattern. Residues at the proposed PHI in one trial of one metabolite were at the limit of quantitation (0.003 ppm), so the LOQ was used. The metabolites were assumed to have equal toxicity to the parent compound, so the total anticipated residue used in the dietary assessment for the chronic analyses was 0.0055 ppm.

iii. *Cancer.* The cancer dietary exposure assessment utilized the same data and assumptions used in the chronic dietary exposure assessment. For dietary exposure to 1,3-dichloropropene, an oral cancer potency factor (Q1* of 1.22×10^{-1} (mg/kg/day)⁻¹) was used to assess cancer risk.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of 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 FFDCA 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 FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient surface water monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for 1,3-dichloropropene and metabolites in drinking water. Because the Agency does not have comprehensive surface water monitoring data, drinking water concentration estimates from surface water sources are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of 1,3-dichloropropene and metabolites. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), the estimated environmental concentrations (EECs) of 1,3-dichloropropene and metabolites for chronic exposures are estimated to be 16.2 parts per billion (ppb). The limited surface water monitoring data available from areas of high use did not show detectable residues of 1,3-dichloropropene in 123 samples.

There is sufficient data for tap water from groundwater wells available for 1,3-dichloropropene and metabolites. A total of 518 wells were selected in the Central Columbia Plateau, Upper Snake River Basin, North Platte River, Albermarle-Pamlico Sound, and the George/Florida basins. The wells were intended to be among the most vulnerable wells available for sampling in each region because they were in high use areas, were among the shallowest in each region, and were located in close proximity to fields that had received 1,3-dichloropropene applications in the recent past. 1,3-Dichloropropene and metabolites were not found above 0.145 ppb in 5,800 samples. 1,3-Dichloropropene or its degradates were detected in 12% of the wells. Only three wells had two detections over the course of the study; no wells had more than two detections. Of the approximately 5,800 samples, only 68 detections were observed for either the parent compound or the metabolites.

Modeled surface water estimates of drinking water concentrations and the maximum ground water concentration from monitoring data were directly entered into the dietary exposure model. For chronic dietary risk assessment, the surface drinking water concentration value of 16.2 ppb was used and the ground drinking water concentration value of 0.14 ppb was used to assess the contribution to drinking water.

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).

1,3-Dichloropropene is not registered for use on any sites that would result in residential exposure. However, due to the volatility of 1,3-dichloropropene, residential bystander exposure may occur when 1,3-dichloropropene is applied to agricultural fields near residential areas. Residential bystander exposure may occur because of emissions from treated fields. These emissions can travel to non-target areas and are referred to as bystander exposure. Bystander exposure can occur as a result of being in contact with residues that are emitted from a known single source (e.g., a single application to an agricultural field near a residential area) and from multiple sources (e.g., applications to numerous agricultural fields) within a localized agricultural region (ambient air exposure).

i. *Inhalation exposure from a single source.* Acute exposures to bystanders from single post-plant agricultural field fumigation events and their associated risks were calculated using the distributional/probabilistic modeling method. Distributional modeling was done with the Probabilistic Exposure and Risk Model for Fumigants (PERFUM). Exposures were also analyzed using the actual field study data (i.e., the monitoring method). Additional information on the methods used to assess bystander risks are given in Section 6.1.1 from the Phase 5 Registration Eligibility Decision.: *Methods Used to Calculate Bystander Exposures and Risks From Known Sources* located at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2005-0124-0052, page 27.

a. Acute exposure was estimated by using the maximum 24-hour time-weighted average (TWA) from each field volatility study.

b. Short-term exposure was estimated by using the highest 7-day average for each direction from each field volatility study.

c. Intermediate-term exposures (consecutive exposures lasting 30 days to several months) is expected to be less likely since 1,3-dichloropropene products are only used 1 to 2 times per field each year.

d. Chronic exposure is not expected since it is unlikely that bystanders will be continually exposed to significant concentrations of 1,3-dichloropropene for 6 consecutive months or longer.

Chronic exposure from multiple (ambient air) sources is more likely and described in section 3 (ii)(c).

e. Cancer risks to 1,3-dichloropropene were estimated for multiple (ambient air) sources as that exposure scenario is more representative of a lifetime of exposure and are described in the following section 3(ii)(d).

ii. *Inhalation exposure from ambient air sources.* Exposure to 1,3-dichloropropene from ambient air was evaluated using monitoring data from California. These data reflect existing pre-plant fumigation uses that are applied at rates over 10 times the rate of the proposed post-plant fumigation use on grapes. These data consist of two basic types that include targeted monitoring that occurred in a high use area during the season of use. The other type of data was collected as part of the routine Toxic Air Contaminant (TAC) program and focus on background levels in urban environments.

a. Acute exposure was estimated by using the maximum 24-hour time-weighted average (TWA) from the monitoring data.

b. Short-term and intermediate-term exposures were estimated by comparing the mean of the weekly mean estimate from the monitoring data.

c. Chronic exposures were calculated using the targeted regional source ambient data. These calculations should be considered as rangefinder estimates of exposure only because of a lack of monitoring studies specifically designed for this purpose. Short- and intermediate-term estimates were amortized to reflect a potential for exposure of 180 days out of each calendar year in order to calculate chronic estimates of exposure. This was based on the approximate use patterns for 1,3-dichloropropene over a year in high use areas. Results based on all of these calculations, as indicated above, do not represent a risk concern to the Agency and in most cases risks were far below the target level of concern (e.g., by orders of magnitude). There were no ambient monitoring studies targeting areas of high use that collected air samples over an entire year that would be considered representative of a chronic exposure pattern. In these studies the focus was more on the actual season of use so these data were typically collected for only 9 weeks or so which represents the duration of the typical application season. However, in order to be able to evaluate the possibility of chronic exposures in high use areas the Agency utilized the seasonal mean of means from the high use areas and supposed that exposures could be maintained at this rate for a

sustained period of 6 months which is twice as long as a normal application season. This approach does have some uncertainty associated with it but the Agency believes that this approach does not underestimate exposure because monitoring data were collected in the season of use in areas of high use. Additionally, risks calculated based on this method, as indicated above, are typically well below the Agency's level of concern. In addition to using the targeted monitoring data, the Agency also used the urban background monitoring data to calculate chronic risks. In this case, the data were intentionally designed to be used to evaluate longer-term exposure levels. Many of the samples collected in this network did not even contain measurable residues over the course of the monitoring years in question but chronic risks were still evaluated as a precautionary measure.

d. For cancer risk assessment, the lifetime average daily exposure (LADE) was calculated using the mean of weekly means and assumed that exposure lasts the length of the longest monitoring period (9 weeks/63 days).

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA 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 1,3-dichloropropene and any other substances and 1,3-dichloropropene does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that 1,3-dichloropropene has 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 FFDCA 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 UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no evidence (quantitative or qualitative) of susceptibility and no residual uncertainties with regard to pre- and/or post-natal toxicity following *in utero* exposure to rats or rabbits and pre- and/or post-natal exposures to rats.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

- i. The toxicity database for 1,3-dichloropropene is complete.
- ii. There is no indication that 1,3-dichloropropene is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that 1,3-dichloropropene results in increased susceptibility following *in utero* and/or post-natal exposure in rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated and average anticipated residues. Conservative surface water modeling estimates were used, and sufficient monitoring data were used to assess ground water concentrations. There are no residential uses of 1,3-dichloropropene and conservative modeling was used to estimate bystander exposure. These assessments will not underestimate the exposure and risks posed by 1,3-dichloropropene and metabolites.

E. Aggregate Risks and Determination of Safety

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 UFs. 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 margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For the acute, short-, intermediate-, and long-term assessments, the toxicity endpoints selected for inhalation and dietary exposures should not be aggregated since no common endpoints were identified at the LOAEL in studies conducted via the oral or inhalation routes. 1,3-Dichloropropene has been classified as likely to be carcinogenic to humans via the oral and inhalation routes. However, the types of tumors observed in the inhalation and oral studies were different. Therefore, the oral and inhalation exposures were not aggregated.

1. *Acute risk.* An endpoint was not selected for acute dietary risk assessment because there were no effects attributable to a single dose (exposure) via the oral route. Therefore, 1,3-dichloropropene is not expected to pose an acute dietary risk.

For residential bystander acute inhalation risk resulting from exposure to a single source, the lowest acute MOE was 400 based on the application rate in the field volatility data and the lowest acute MOE was 160 based on the maximum label rate. The risk estimates did not exceed the level of concern using the PERFUM modeling method. For residential bystander acute inhalation risk resulting from exposure to ambient air sources, the lowest acute MOE was 2,700 based on California ambient air monitoring data. The MOEs do not exceed the Agency's level of concern of < 30.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to 1,3-dichloropropene and metabolites from food and water (ground water sources) will utilize < 1% of the cPAD for the most highly exposed population group (children 1 to 2 years old) and from food and water (surface water sources) will utilize < 5% of the cPAD for the most highly exposed population group, infants < 1 year old.

Residential bystander chronic inhalation exposure from a single source is not expected to occur and therefore, does not pose an inhalation risk. For residential bystander chronic inhalation risk resulting from exposure to ambient air sources, the lowest chronic MOE was 130 based on California ambient air monitoring data. The MOE does not

exceed the Agency's level of concern of < 30.

3. *Short-term risk.* For residential bystander short-term inhalation risk resulting from exposure to a single source, the lowest short-term MOE was 60 based on the application rate in the field volatility data and based on the maximum label rate. For residential bystander short-term inhalation risk resulting from exposure to ambient air sources, the lowest short-term MOE was 1,700 based on California ambient air monitoring data. The MOEs do not exceed the Agency's level of concern of < 30.

4. *Intermediate-term risk.* Residential bystander intermediate-term inhalation exposure from a single source is unlikely to occur and therefore, does not pose an inhalation risk. For residential bystander intermediate-term inhalation risk resulting from exposure to ambient air sources, the lowest intermediate-term MOE was 70 based on California ambient air monitoring data. The MOE does not exceed the Agency's level of concern of < 30.

5. *Aggregate cancer risk for U.S. population.* The aggregated food and water risk represent upper bound risks for a person living in agricultural areas where 1,3-dichloropropene is used extensively or where a person obtains drinking water from an aquifer that led directly from an area where 1,3-dichloropropene was used. The aggregate chronic dietary cancer risk estimates for the general U.S. population resulting from exposure to 1,3-dichloropropene and metabolites in food and water (ground water sources) is 7×10^{-7} and from exposure to 1,3-dichloropropene and metabolites in food and water (surface water sources) is 4×10^{-5} .

Although risk for drinking water from surface water sources for 1,3-dichloropropene exceeds the Agency's level of concern (risk estimates generally in the range of 1 in 1 million, interpreted as > 1 to 3×10^{-6}); it should be noted that concentrations of 1,3-dichloropropene in tap water from ground water wells were approximately 100 times lower than those found in the field ground water study and several orders of magnitude lower than modeled estimates of 1,3-dichloropropene in groundwater. Therefore, it is highly likely that actual drinking water concentrations of 1,3-dichloropropene from surface water sources would also be much lower. 1,3-Dichloropropene and its metabolites are highly volatile compounds, and the models used to generate surface water and ground water estimates are not designed for volatile chemicals. The

limited surface water monitoring data available in areas of high use do not show any detections of 1,3-dichloropropene and its degradates. Therefore, the Agency does not have a concern for the aggregate cancer risk from oral exposures to 1,3-dichloropropene and its metabolites.

Cancer risk was estimated using 1,3-dichloropropene ambient air monitoring data collected from over 20 sites over multiple years to estimate exposure over a lifetime. These sites were in areas of high use and in urban environments. The cancer risk estimates for all but one monitoring site, in a high use area, ranged from 2×10^{-6} to 9×10^{-8} , which are below the Agency's level of concern. The monitoring data for the one site resulted in a risk estimate of 6×10^{-6} , which does exceed the Agency's level of concern. However, risks calculated using data from the same site in the following year was almost two orders of magnitude lower. Therefore, over a lifetime of exposure, the risk estimates would likely be below the level of concern. It should be noted that in more populated urban environments, air concentrations were below the analytical limit of detection in 21 of 28 sites/year combinations considered. In the remaining seven site/year combinations, values were measured but did not result in cancer risks of concern. Therefore, the Agency does not have a concern for the cancer risk from 1,3-dichloropropene.

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 1,3-dichloropropene and metabolites residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Dow AgroSciences, LLC submitted a gas chromatography/mass spectroscopy (GC/MS) method, Method GRM 99.09.R1, for the determination of residues of *cis*- and *trans*-1,3-dichloropropene. The method was adequately validated using fortified samples of grape. Recoveries of *cis*-1,3-dichloropropene ranged from 70% to 114% and recoveries of *trans*-1,3-dichloropropene ranged from 77% to 113% from samples fortified at 0.003, 0.010, 0.050, and 0.50 ppm. The fortification levels used in method validation are adequate to bracket expected residue levels. Adequate independent laboratory validation (ILV) data were submitted for Method GRM 99.09.R1 using samples of grape.

Dow AgroSciences, LLC submitted a GC/MS method, Method GRM99.18, for the determination of residues of 3-chloroallyl alcohol and 3-chloroacrylic acid. The validated LOQ is 0.003 ppm for each analyte in grape. The method was adequately validated using fortified samples of grape. Recoveries of *cis*-3-chloroallyl alcohol ranged from 74% to 90%, recoveries of *trans*-3-chloroallyl alcohol ranged from 82% to 95%, recoveries of *cis*-chloroacrylic acid ranged from 93% to 98%, and recoveries of *trans*-chloroacrylic acid ranged from 91% to 96% from samples fortified at 0.003, 0.006, and 0.030 ppm. The fortification levels used in method validation are adequate to bracket expected residue levels. The Agency has tentatively concluded that the metabolite method is suitable for enforcement.

Adequate enforcement methodology (GC/MS) is available to enforce the tolerance expression. 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.

B. International Residue Limits

There are no Canadian or Codex Maximum Residue limits for residues of 1,3-dichloropropene for any commodity.

C. Conditions

1. An independent laboratory validation of Method GRM 99.18 and multi-residue method testing will be required as confirmatory data.

2. In order to refine the exposure estimates from PRZM-EXAMS, the following data will be required: an aerobic soil metabolism study on additional soils (parent and metabolites); an aerobic aquatic metabolism study (parent and metabolites); an aqueous photolysis study (indirect and parent); a soil photolysis study (parent); and a photolysis/oxidation in air study (parent).

V. Conclusion

Therefore, the tolerance is established for combined residues of *cis*- and *trans*-1,3-dichloropropene, *cis*- and *trans*-3-chloroacrylic acid, and *cis*- and *trans*-3-chloroallyl alcohol, in or on grape at 0.018 ppm.

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: February 1, 2008.

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 180.636 is added to subpart C to read as follows:

§ 180.636 1,3-dichloropropene; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide *cis*- and *trans*-1,3-dichloropropene and its metabolites *cis*- and *trans*-3-chloroacrylic acid, and *cis*- and *trans*-3-chloroallyl alcohol in or on the following commodities.

Commodity	Parts per million
Grape	0.018

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. E8-2480 Filed 2-12-08; 8:45 am]

BILLING CODE 6560-50-S

LEGAL SERVICES CORPORATION

45 CFR Part 1611

Income Level for Individuals Eligible for Assistance

AGENCY: Legal Services Corporation.

ACTION: Final rule—correction.

SUMMARY: The Legal Services Corporation ("Corporation") is required by law to establish maximum income levels for individuals eligible for legal assistance. On January 30, 2008 the Corporation issued a document updating the specified income levels to reflect the annual amendments to the Federal Poverty Guidelines as issued by the Department of Health and Human Services. This notice corrects a typo appearing in the supplementary information, but does not affect the income levels set forth in the charts. Specifically, in the sentence in the last paragraph of the **SUPPLEMENTARY INFORMATION**, 73 FR 5458, Jan. 30, 2008, beginning "These charts are for reference purposes * * *," the first percentage referred to should be "125%" instead of "200%."

DATES: *Effective Date:* This rule is effective as of January 30, 2008.

FOR FURTHER INFORMATION CONTACT:

Mattie Cohan, Senior Assistant General Counsel, Legal Services Corporation, 3333 K St., NW., Washington, DC 20007; (202) 295-1624; mcohan@lsc.gov.

SUPPLEMENTARY INFORMATION: Section 1007(a)(2) of the Legal Services Corporation Act ("Act"), 42 U.S.C. 2996f(a)(2), requires the Corporation to establish maximum income levels for individuals eligible for legal assistance, and the Act provides that other specified factors shall be taken into account along with income.

Section 1611.3(c) of the Corporation's regulations establishes a maximum income level equivalent to one hundred and twenty-five percent (125%) of the Federal Poverty Guidelines. Since 1982, the Department of Health and Human Services has been responsible for updating and issuing the Federal Poverty Guidelines. The revised figures for 2008 are equivalent to 125% of the current Federal Poverty Guidelines as published on January 23, 2008 (73 FR 3971).

LSC published the charts listing income levels that are 200% of the Federal Poverty Guidelines at 73 FR 5458, Jan. 30, 2008. These charts are for reference purposes only as an aid to grant recipients in assessing the financial eligibility of an applicant whose income is greater than 125% of the applicable Federal Poverty