revised on April 24 and August 18, 1998, December 21, 1999 and December 28, 2000.

(2) EPA approves the contingency plans for failure to meet rate of progress in the Baltimore severe ozone nonattainment area for milestone years 1999, 2002 and 2005. These plans were submitted by the Secretary of the Maryland Department of the Environment on December 24, 1997, as revised on April 24 and August 18, 1998, December 21, 1999 and December 28, 2000.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301176; FRL–6803–7]

RIN 2070–AB78

Zoxamide 3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH-1455 and RH-141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH-1452 and RH-141452 in or on tomato and cucurbit vegetables group. Rohm and Haas Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 26, 2001. Objections and requests for hearings, identified by docket control number OPP–301176, must be received by EPA on or before November 26, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI.. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301176 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305-7740; and e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301176. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 24, 2000, 65 FR 51612 (FRL–6739–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–-170) announcing the filing of a pesticide petition (PP 9F5058) for tolerance by Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19108-2399. This notice included a summary of the petition prepared by Rohm and Haas, the registrant. There were no comments received in response to the notice of filing. A correction to the notice of filing was published in the **Federal Register** on December 15, 2000, 65 FR 78490 (FRL–6756–3).

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for combined residues of the fungicide zoxamide 3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide, and its metabolites, in or on tomatoes and cucurbit vegetables group at 2.0 part per million (ppm).

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) 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) 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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2), for a tolerance for combined residues of zoxamide and its metabolites 2,4-dichloro-1,4-benzenedicarboxylic acid (RH-1455 and RH-141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH-1452 and RH-141452) on tomatoes at 2.0 ppm and cucurbit vegetables group at 1.0 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 nature of the toxic effects caused by zoxamide are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1. ACUTE TOXICITY OF ZOXAMIDE - TECHNICAL (RH-117,281)

Guideline No.	Study Type	Results	Toxicity Category
870.1100	Acute Oral-Rat	LD_{50} > 5,000 mg/kg (males and females, combined)	IV
870.1100	Acute-Oral-Mouse	LD_{50} > 5,000 mg/kg (males and females, combined)	IV
870.1200	Acute Dermal-Rat	LD_{50} > 2,000 mg/kg (males and females, combined)	III
870.1300	Acute Inhalation-Rat	LC_{50} > 5.3 mg/L (males and females, combined)	IV
870.2400	Primary Eye Irritation-Rabbit	Moderate irritant; Corneal opacity on 6/6 rabbits with resolution by day 7. Iritis on 1/6 rabbits at 24 hours with resolution by 48 hours. Conjunctivitis on all rabbits at one hour with resolution by day 7.	III
870.2500	Primary Skin Irritation-Rabbit	Not an irritant	IV
870.2600	Dermal Sensitization: Maximization-Guinea pig	Strong sensitizer. Maximization Test: 100% treated showed erythema.	NA
870.2600	Dermal Sensitization: Buehler's Method-Guinea pig	Strong sensitizer. Buehler's Test: 80–90% treated showed erythema, grade 3 out of possible 4, appearing at 3rd induction phase and challenge phase.	NA

The primary target organ for oral exposure is the liver. In chronic and subchronic dog studies, liver and thyroid weights were increased along with liver histopathological changes and increases in alkaline phosphatase in the chronic study. There was no evidence of developmental or reproductive toxicity. The data demonstrate no increase sensitivity of rats or rabbits to *in utero* or early postnatal exposure to zoxamide. Carcinogenicity studies in rats and mice did not show increased incidence of spontaneous tumor formation. Zoxamide is classified as ''not likely'' human carcinogen. There was no evidence of neurotoxicity in the acute or subchronic neurotoxicity studies or in any other study in the data base. The toxicity data base for zoxamide is complete. See the following Table 2 for a discussion EPA's findings.

TABLE 2.—TOXICITY PROFILE OF ZOXAMIDE TECHNICAL

Guideline No.	Study Type (All Studies Acceptable)	Results
870.3100	90–Day oral toxicity rodents-mouse	NOAEL = 1,666 mg/kg/day; LOAEL not established

TABLE 2.—TOXICITY PROFILE OF ZOXAMIDE TECHNICAL—Continued

Guideline No.	Study Type (All Studies Acceptable)	Results
870.3150	90–Day oral toxicity in nonrodents-dog	NOAEL = 62 mg/kg/day in females, 281 mg/kg/day in males. LOAEL = 322 mg/kg/day in females and 1,139 mg/kg/day in males based on increased liver weights, hepatocellular hypertrophy (males), decrease in albumin and albumin/golbulin ratios (males).
870.3200	28-Day dermal toxicity-rat	Systemic: NOAEL ≥1,000 mg/kg, LOAEL not established; Dermal: NOAEL not established LOAEL < 150 mg/kg/day based on dermal scabbing increase with dosage in males and females, and epidermis of treated skin sites showed hyperplasia, hyperkeratosis, and inflammation.
870.3700a	Prenatal developmental in rodents-rat	Maternal NOAEL = 1,000 mg/kg/day; LOAEL > 1,000 mg/kg/day. Developmental NOAEL = 1,000 mg/kg/day LOAEL > 1,000 mg/kg/day.
870.3700b	Prenatal developmental in nonrodents-rabbit	Maternal NOAEL = 1,000 mg/kg/day; LOAEL > 1,000 mg/kg/day. Developmental NOAEL = 1,000 mg/kg/day; LOAEL > 1,000 mg/kg/day.
870.3800	Reproduction and fertility effects-rat	Parental/Systemic NOAEL = 409 mg/kg/day in females, 1,474 mg/kg/day in males; LOAEL = 1,624 mg/kg/day based on female decreased body weight and body weight gains. Reproductive NOAEL ≥ 2,091 mg/kg/day in males, 2,239 mg/kg/day in females; LOAEL = not established. Offspring NOAEL ≥ 2,091 mg/kg/day in males, 2,239 mg/kg/day in females; LOAEL = not established.
870.4100b	Chronic toxicity dogs	NOAEL = 50 mg/kg/day in males, 48 mg/kg/day in females; LOAEL = 255 mg/kg/day in males, 278 mg/kg/day in females based on decreased body weights, increased liver and thyroid weights, and increased alkaline phosphatase.
870.4300	Chronic/Carcinogenicity rats	NOAEL = 1,058 mg/kg/day; LOAEL = not established. No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 1,021 mg/kg/day in males, 1,289 mg/kg/day in females; LOAEL = not established. No evidence of carcinogenicity
870.5265	Gene Mutation	Non-mutagenic when tested up to 5,000 μg/plate, in presence and absence of activation, in *S. typhimurium*.
870.5300	Cytogenetics	Non-mutagenic at the HGPRT locus in CHO cells tested up to 65 μg/mL, in presence and absence of activation.
870.5375	Chromosome aberration	Did not induce structural chromosome aberration up to limit of toxicity (100 μg/mL), but did induce increased levels of numerical aberrations, in presence and absence of activation.
870.5395	Micronucleus	Non-mutagenic in mouse bone marrow micronucleus assay up to 2,000 mg/kg.
870.6200a	Acute neurotoxicity screening battery-rat	NOAEL = 2,000 mg/kg/day; LOAEL = not established.
870.6200b	Subchronic neurotoxicity screening battery-rat	NOAEL = 1,509 mg/kg/day in males, 1,622 mg/kg/day in females; LOAEL = not established.
870.7485	Metabolism and pharmacokinetics - rat	120 hours post-dosing, 96–102% recovered from the low and high single-dose groups. Fecal excretion was the primary route of elimination. Parent compound was the principal component excreted, a total of 36 metabolites were detected in the urine and feces.
870.7600	Dermal penetration-rat	Total dermal absorption rate after 10–hour is 8.8% (includes amount on skin after wash).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10x to account for interspecies differences and 10x for intra species differences. The Agency evaluated the available hazard and exposure data for zoxamide and made the recommendation for the FQPA safety factor to be used in human health risk assessments (as required by the FQPA of August 3, 1996). The Agency concluded that the FQPA safety factor could be removed (i.e., reduced to 1x) in assessing the risk posed by this

chemical because: (1) There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; (2) A development neurotoxicity study conducted with zoxamide is not required; and (3) The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children. Additionally, there are currently no residential uses.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10x to account for interspecies differences and 10x for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for zoxamide used for human risk assessment is shown in the following Table 3:

TABLE 3.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ZOXAMIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (general population including infants and children)	None	None	No appropriate endpoint was identified by the HIARC on 11/18/99 for acute dietary exposure. Did not identify hazard.
Chronic Dietary (all populations)	NOAEL= 48 mg//kg/day UF = 100 Chronic RfD = 0.48 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD/FQPA SF = 0.48 mg/kg/day	Chronic Toxicity Study - Dog LOAEL in males/females = 255/277 mg/kg/day based on body weight changes, increases in liver and thyroid weights, and increases in alkaline phosphatase.
Short-, Intermediate-, and Long-Term Dermal (Occupational/ Residential)	none	No systemic toxicity was seen at the limit dose (1000 mg/kg/day). Did not identify hazard.	28-Day Repeated Dose Dermal - Rat
Any time period Inhalation (Occupational/Residential)	oral NOAEL= 48 mg/kg/day Use route-to-route extrapolation (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational/Residential)	Chronic Toxicity Study - Dog LOAEL in males/females = 255/277 mg/kg/day based on body weight changes, increases in liver and thyroid weights, and increases in alkaline phosphatase.

* UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowestobserved adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin ofexposure, LOC = level of concern. The reference to the FQPA Safety Factor refers to any additional safety factorretained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR part 180) for the combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH-1455 and RH141455) and (3,5-(dichloro-1,4-hydromethylbenzoic acid (RH-1452 and RH-141452, in or on potatoes and Zoxamide on grapes. Risk assessments were conducted by EPA to assess dietary exposures from zoxamide in food as follows:

i. *Acute exposure.* Acute dietary 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 one day or single exposure. Based on available data, a suitable endpoint for acute dietary risk assessment was not identified since no effects were observed in oral toxicity studies (including developmental studies) which could be attributed to a single-dose exposure. Therefore, an acute dietary risk assessment was not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Chronic assessments use an average of the reported consumption values for each food form of a commodity multiplied by the residue concentration value, in this case a tolerance value, to estimate chronic dietary exposure.

The Tier I chronic analysis for zoxamide is a conservative estimate of the dietary exposure using tolerance-level residues of 100% crop-treated for all commodities. The chronic analysis was performed assuming tolerance level

residues for tomatoes and curcurbit vegetables at 2.0 and 1.0 ppm, respectively and 100% crop treated was assumed for all other commodites. The tolerance level residues for processed commodities were based on the actual processing data, the DEEM default concentration factors for tomato paste and puree were set to 1x. Residues did not concentrate in tomato processed fractions in this study. The highest resulting dietary estimate was 1.7% of the cPAD for children. 1-6 years old. For chronic dietary risk estimates the level of concern is >100% CPAD. Even without refinements, the estimated risk from chronic dietary exposure to zoxamide, as represented by the % cPAD, is below the level of concern for the population and all population subgroups.

TABLE 4.—CHRONIC DIETARY EXPOSURE ESTIMATES

Population subgroup[1]	Exposure, mg/kg/day	%cPAD[2]
U.S. population	0.0031	<1
All infants <1 year)	0.0018	<1
Children 1-6 yrs[3]	0.0084	1.7
Females 13-50 yrs	0.0024	<1
Males 13-19 yrs	0.0026	<1

[1] The subgroups listed are: (1) The U.S. Population (total); (2) those for infants and children; and, (3) the most highly exposed of the adult females and males subgroups (in this case, Females, ≤13 years, nursing)

[2] Percent Chronic PAD = (Exposure ÷ Chronic PAD) x 100%.

[3] There are no other subgroups, with the exception of Children, 1 to 6 years old, for which the percentage of the Chronic PAD occupied is greater than that occupied by the subgroup U. S. Population (total).

iii. *Cancer*. Zoxamide is not mutagenic in Ames assays, in CHO cells assay at the Hypoxonthine guanine phosphoribosyle transferase (HGPRT) locus, and in the mouse bone marrow micronucleus assay. Zoxamide did not induce structural chromosome aberrations in cultured CHO cells treated up to the limit of toxicity, but did induce increased levels of numerical aberrations. Carcinogenicity studies in rat and mice did not show increased incidence of spontaneous tumor formation. The Agency classified zoxamide as not likely to be a human carcinogen. Thus a cancer risk assessment is not required for zoxamide.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for zoxamide in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of zoxamide.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/ EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/ EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to zoxamide they are further discussed in the aggregate risk sections below.

Based on the GENEEC, and PRZM/ EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of zoxamide for acute and chronic exposures are as follows:

A drinking water risk assessment was not performed as the proposed use rates do not exceed those already assessed. Therefore new dietary risk estimates from drinking water sources were not performed. Drinking water monitoring data are not available for zoxamide. No new EECs were provided for cucurbits and tomatoes because the application rates for these new uses approaches the maximum rate for grapes.

Tier I (GENEEC) modeling estimates that zoxamide residues (zoxamide + degradation products) in surface water, from aerial and ground application, are not likely to exceed 48.3 and 45.1 µg/ L for the 56 day average concentration (chronic) for grape and potato uses, respectively. However, it is the Agency's policy to divide chronic Tier 1 GENEEC EECs by a factor of 3 for comparison to DWLOCs. Therefore, the chronic surface water EECs based on GENEEC are 16.1 and 15 µg/L for grape and potato uses, respectively.

Tier II (PRZM/EXAMS) surface water modeling for zoxamide residues (zoxamide + degradation products), using the index reservoir with the percent cropped area, predicts the 1 in 10 year annual average (non-cancer chronic) concentration of zoxamide residues from grapes is not likely to exceed 21.8 µg/L and from potatoes is not likely to exceed 6.2 µg/L.

The SCI-GROW predicted concentration of zoxamide residues (zoxamide + degradation products) in shallow ground water is not expected to exceed 2.07 µg/L.]

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).

Zoxamide is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) 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.''

EPA does not have, at this time, available data to determine whether zoxamide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, zoxamide 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 zoxamide 3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional 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 data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Conclusion*. There is a complete toxicity data base for zoxamide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10x safety factor to protect infants and children should be removed. The FQPA factor is removed because:

i. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure;

ii. A developmental neurotoxicity study conducted with zoxamide is not required; and

iii. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children. Additionally, there are currently no residential uses.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Based on the data, EPA concluded that zoxamide does not pose an acute risk.

2. *Chronic risk*. The resulting dietary food exposures, from cucurbits and tomatoes, occupy <1% of the Chronic PAD for all population subgroups included in the analysis, except for children (1 to 6 years old) which is the highest exposed subgroup. The exposure for children (1 to 6 years old) utilizes 1.7% of the cPAD. The results of this dietary exposure analysis should be viewed as very conservative (health protective). Refinements such as use of percent crop-treated information and/or anticipated residue values would yield even lower estimates of chronic dietary exposure.

The EECs provided by the Agency for assessing chronic aggregate dietary risk are 2.07 µg/L (for ground water, based on SCI-GROW) and 21.8 µg/Lin surface water, based on PRZM/EXAMS modeling, 1 in 10 year annual average). The back-calculated DWLOCs for cucurbits and tomatoes (Table 5) for assessing chronic aggregate dietary risk range from 4800 µg/L for the population subgroup with the highest food exposure (Children, 1 to 6 years old) to 16,800 µg/L for the U.S. population (total) and Males 13-19 years.

The SCI-GROW and PRZM/EXAMS chronic EECs are less than the Agency's level of comparison (the DWLOC value for each population subgroup) for zoxamide residues in drinking water as a contribution to chronic aggregate exposure. Thus, the Agency concludes with reasonable certainty that residues of zoxamide in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from zoxamide residues in food and drinking water will not exceed the Agency's level of concern (100% of the Chronic PAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the Chronic PAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, very conservative, and very protective of human health. There are no residential uses for zoxamide that result in chronic residential exposure to zoxamide.

TABLE 5.—CHRONIC DWLOC CALCULATIONS

Population Subgroup[1]	Chronic Scenario					
	cPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Maximum Water Exposure (mg/kg/day)[2]	EEC Groundwater (µg/L)[3]	EEC Surface-water (µg/L)[4]	Chronic DWLOC (µg/L)[5]
U.S. population	0.48	0.0031	0.48	2.07	21.8	16,800
Children 1-6 yrs	0.48	0.0018	0.48	2.07	21.8	4,800
Females 13-50	0.48	0.0084	0.48	2.07	21.8	14,400
Males 13-19	0.48	0.0026	0.48	2.07	21.8	16,800

[1] The exposure for the highest representative population subgroup was reported. Body weights varied by subgroup: 70 kg for an adult male; 60 kg for an adult female; 10 kg for a child.
[2] Maximum Water Exposure (mg/kg/day) = cPAD (mg/kg/day) - Dietary Exposure from DEEM (mg/kg/day)
[3] The value from the model and crop producing the highest level was used (i.e. SCI-GROW value).
[4] The value from the model and crop producing the highest level was used (i.e. PRZM/EXAMS value for grapes).
[5] DWLOC(µg/L) = [maximum water exposure (mg/kg/day) x body weight (kg)]/[water consumption (L) x 10^{-3} mg/µg]

3. *Short-term risk*. The Agency did not identify a short-term dermal endpoint for zoxamide. There are no residential uses proposed for this fungicide, short term aggregate risk assessments based on exposure from

oral, inhalation, and dermal routes. For these reasons, no short term risk is expected.

4. *Intermediate-term risk*. The Agency did not identify an intermediate -term dermal endpoint for zoxamide. There are no residential uses proposed for this fungicide, intermediate-term aggregate risk assessments based on exposure from oral, inhalation and dermal routes. For these reasons, no intermediate-term risk is expected.

5. *Aggregate cancer risk for U.S. population*. The Agency classified zoxamide as not likely to be a human carcinogen. Therefore, no cancer risk is expected.

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, and to infants and children from aggregate exposure to zoxamide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner proposes a GC/ECD method, with LOD and validated LOQ of 0.003 and 0.01 ppm respectively, for the enforcement of tolerances on cucurbits and tomatoes. A GC/MSD method is proposed as a confirmatory method. Method validation recoveries indicate that the GC/ECD method adequately recovers residues of zoxamide from cucurbits, tomatoes, and tomato processed commodities. Adequate confirmatory method validation, radiovalidation, and independent method validation have been submitted for this method. The submitted GC/ECD method is similar to the enforcement method proposed for grapes and potatoes under PP 9F05058 which has been forwarded to ACB/BEAD for a petition method validation . A petition method validation was also requested for the GC/ECD enforcement method proposed for tomatoes and cucurbits (PP 0F06093).

The methods were successfully validated for tomatoes and cucurbits in one trial by the independent laboratory. A slight modification was made but only with the instrumental parameters. For tomatoes, the head pressure in the oven ramp was lowered from 13 to 7.5 psi because hydrogen was substituted as the carrier gas and the total detector flow was set at 15 mL/min of N_2 instead of 60 mL/min. For cucumber, the detection temperature was set at 315°C instead of 300 °C and the total detector flow was set at 12 mL/min instead of 60mL/min.). The changes were found necessary to optimize sensitivity of the Varian 3500 ECD and allow detection of zoxamide at the LOQ of 0.01 ppm. Apparent residues of zoxamide were nondetectable (<0.01 ppm) in/on two control samples each of cucumbers and tomatoes. The recoveries were between 70 - 120% with an RSD below 15% which were within the acceptable limits. Extraction of 6 samples took about 6-8 hours and analysis of samples and standards took about 5-6 hours.

Plant commodity samples collected from the field, processing, and storage stability studies were analyzed for residues of zoxamide using either the GC/ECD or GC/MSD method. The concurrent method recoveries indicate that both methods are adequate for data collection for cucurbits and tomatoes.

The methods are adequate for a conditional registration pending successful validation results and comments from ACB/BEAD.

The Residue Analytical Method - Plant Commodities are adequate for a conditional registration pending successful validation results and comments from The Analytical Chemistry Branch Laboratories, BEAD (7503C), Office of Pesticides Programs. Upon successful completion of the EPA validation and the granting of this registration, the method will be forwarded to FDA for publication in a future revision of the Pesticide Analytical Manual, Vol. II (PAM-II). Prior to publication and upon request , the validation will be available the Analytical Chemistry Branch (ACB), BEAD (7503C) Environmental Science Center, 701 Mapes Road, Ft. George C. Meade, MD 29755-5350. Contact Francis D. Griffith, Jr., telephone (410) 305-2905, e-mail: griffith.francis@epa.gov. The analytical standards are also available from the EPA National Pesticide Standard Repository at the same location.

The MRMs are adequate for enforcement of the proposed tolerances for zoxamide in/on cucurbits and tomatoes. The submission has been forwarded to FDA for complete evaluation in conjunction with the earlier petition.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) or tolerances for residues of zoxamide in/on tomatoes and cucurbits. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances discussed in this petition review.

C. Conditions

Additional storage stability data are required for residues of zoxamide in/on cucurbit vegetables stored 15.6 months, tomato fruit stored 15.2 months and tomato paste and puree stored 11.5 months. The additional storage stability data for tomatoes, tomato paste and puree and cucumber is a condition for the registration of zoxamide for use on tomatoes and cucurbits.

V. Conclusion

Therefore, the tolerance is established for combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH-1455 and RH-141455) and 3,5-dichloro-4-hydroxymethlbenzoic acid (RH-1452 and RH-141452), in or on tomatoes at 2.0 ppm and cucurbit vegetable group at 1.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301176 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 on or before November 26, 2001.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in

connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301176, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the

Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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 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: September 13, 2001.

Peter Caulkins,

Acting 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), 346(a) and 371.

2. Section 180.567 is amended by alphabetically adding commodities to the table in paragraph (a)(2) to read as follows:

§ 180.567 Zoxamide;tolerance for residues.

(a) * * *

(2)* * *

Commodity	Parts per million
Cucurbit vegetable group	1.0
* * * * *	
Tomato	2.0

* * * * * *

[FR Doc. 01–23640 Filed 9–25–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7065–7]

California: Final Authorization of Revisions to State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final determination on application of California for Final Authorization of Revisions to State Hazardous Waste Management Program.

SUMMARY: California has applied for final authorization of certain revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency (EPA) has reviewed California's application and has reached a final determination that the revisions to California's hazardous waste program satisfy all of the requirements necessary to qualify for final authorization. Thus, with respect to these revisions, EPA is granting final authorization to the State to operate its program subject to the limitations on its authority retained by EPA in accordance with the Hazardous and Solid Waste Amendments of 1984.

EFFECTIVE DATE: Final authorization for the revisions to California's hazardous waste management program shall be effective at 1 p.m. on September 26, 2001.

FOR FURTHER INFORMATION CONTACT: Rebecca Smith, WST–3, U.S. EPA Region 9, 75 Hawthorne Street, San Francisco 94105–3901, (415) 744–2152.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA Section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, states must change their programs and ask EPA to authorize the changes. Changes to state programs may be necessary when Federal or state statutory or regulatory authority is modified or when certain other changes occur. Most commonly, states must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

California initially received final authorization on July 23, 1992, effective August 1, 1992 (57 FR 32726), to implement the RCRA hazardous waste management program. This ''base program authorization'' authorized California's RCRA program based on California statutory and regulatory provisions enacted and adopted prior to December 20, 1991, the date of California's authorization application. On January 31, 2000, California submitted a final complete program revision application, seeking authorization of their changes in accordance with 40 CFR 271.21.

B. What Were the Comments and Responses to EPA's Proposal?

On June 20, 2001, EPA published a tentative determination announcing its intent to grant California final authorization for the revisions to its base program. Further background on the tentative decision to grant authorization appears at Vol. 66, No. 119, June 20, 2001 at pages 33037–33046.

Along with the tentative determination, EPA announced the availability of the application for public comment. EPA received four sets of written comments during the public comment period. One of the four commenters submitted relatively lengthy comments regarding EPA's tentative determination (22 pages total). The other three commenters submitted relatively brief comments (1–2 pages total, each), which generally endorsed the comments submitted by the first commenter. The first commenter also submitted an 8 page supplement to its comments well after the close of the public comment period. These comments were received by EPA on September 4, 2001, although the public comment period closed on July 20, 2001. The significant issues raised by the commenters and EPA's responses are summarized below. EPA has included a response to the supplemental comments as well, (*see* Response to Comment #3, below).