PART180-[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 180.469 is amended by revising the section heading, and the introductory text of paragraph (a), and by adding alphabetically new commodities to the table in paragraph (a) to read as follows:

§ 180.469 Dichlormid; tolerances for residues.

(a) *General.* Tolerances are established for residues of dichormid; (Acetamide, 2,2-dichloro-*N,N*-di-2-propenyl-)(CAS Reg. No. 37764–25–3) when used as an inert ingredient (herbicide safener) in pesticide formulations in or on the following food commodities:

Commodity	Parts per million	Expiration/ revocation date
* *	* *	*
Corn, sweet, forage	0.05	12/31/05
Corn, sweet, kernel plus cob with husks removed	0.05	12/31/05
Corn, sweet, stover	0.05	12/31/05

* * * * *

[FR Doc. 04–21930 Filed 9–29–04; 8:45 am]

BILLING CODE6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0211; FRL–7367–4]

Cyazofamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the combined residues of cyazofamid and its metabolite CCIM in or on potatoes, tomatoes, cucurbits, and imported wine. ISK Biosciences Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 30, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP–2004–0211. All documents in the docket are listed in the EDOCKET index at*http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.*, 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Janet Whitehurst, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6129; e-mail address:*whitehurst.janet@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 provides 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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/.* To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at*http://www.epa.gpo/opptsfrs/home/guidelin.htm/.*

II. Background and Statutory Findings

In the **Federal Register** of May 7, 2003 (68 FR 24463) (FRL–7305–7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F06305) by ISK Biosciences Corporation, Concord, OH. That notice included a summary of the petition prepared by ISK Biosciences Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the fungicide cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, expressed as cyazofamid, in or on cucurbit vegetables (Group 9) at 0.10 parts per million (ppm), potato at 0.01 ppm, tomato at 0.20 ppm, and grape wine at 1.0 ppm.

Following review of the residue and metabolism data, EPA has made several minor changes to the proposed tolerances. For cucurbits and potatoes, EPA expanded the tolerance expression to cover both cyazofamid and its metabolite CCIM, which is also a residue of concern. This expansion of the toleranceexpression necessitated a raising of the tolerance level for potatoes from 0.01 ppm to 0.02 ppm. No change in the tolerance values was needed for tomatoes. Finally, residue and processing data for grape wine showed that residues might slightly exceed 1.0

ppm; accordingly, the tolerance for grape wine was raised to 1.5 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) 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....''

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 of FFDCA 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) of FFDCA, 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) of FFDCA, for a tolerance for combined residues of cyazofamid on cucurbits at 0.10 ppm, potatoes at 0.01 ppm, tomatoes at 0.2 ppm, and wine grape 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 cyazofamid are discussed in Table 1 of this unit 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.—TOXICITY PROFILE OF CYAZOFAMID [IKF–916] TECHNICAL

Guideline No.	Study Type	Results
870.3100	90–day oral toxicity in rats	NOAEL = 29.5 [M] mg/kg/day LOAEL = 295 [M] mg/kg/day based on increased number of ''basophilic kidney tubules,'' and increased urinary volume, pH, and protein.
870.3150	90–Day oral toxicity in dogs	NOAEL = 1,000 [M/F] mg/kg/day LOAEL = not observed.
870.3200	28–Day dermal toxicity in rats	NOAEL = 1,000 [M/F] mg/kg/day LOAEL = not observed.
870.3700	Prenatal developmental in rats	Maternal NOAEL = 1,000 mg/kg/day LOAEL = not observed Developmental NOAEL = 100 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased incidence of bent ribs.
870.3700	Prenatal developmental in rabbits	Maternal NOAEL = 1,000 mg/kg/day LOAEL = not observed Developmental NOAEL = 1,000 mg/kg/day LOAEL = not observed
870.3800	Reproduction and fertility effects in rats	Parental/Systemic NOAEL = 1,114/1,416 [M/F] mg/kg/day LOAEL = not observed Reproductive NOAEL = 1,114/1,416 [M/F] mg/kg/day LOAEL = not observed Offspring NOAEL = 1,114/1,416 [M/F] mg/kg/day LOAEL = not observed
870.4100	Chronic toxicity in rats	NOAEL = 171/ 856 [M/F] mg/kg/day LOAEL = not observed.
870.4100	Chronic toxicity in dogs	NOAEL = 200 [M/F] mg/kg/day LOAEL = 1,000 [M/F] mg/kg/day based on increased cysts in parathyroids in both sexes and increased pituitary cysts in females.
870.4200	Carcinogenicity rats	NOAEL = 171/ 856 [M/F] mg/kg/day LOAEL = not observed. No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 94.8 [M] mg/kg/day LOAEL = 985 [M] mg/kg/day based on increased incidence of skin lesions including hair loss, body sores, dermatitis, ulceration, and acanthosis. No evidence of carcinogenicity

TABLE 1.—TOXICITY PROFILE OF CYAZOFAMID [IKF–916] TECHNICAL—Continued

Guideline No.	Study Type	Results
870.5100	Gene Mutation Bacterial reverse mutation assay	Negative ± S9 up to 5,000 μg/plate by standard plate and tube preincubation (not cytotoxic but there was precipitation at ≥ 1,500 μg/plate.
870.5300	Gene Mutation Mammalian cell culture	Negative ± S9 up to cytotoxic and precipitating concentration of 100 μg/mL
870.5375	Cytogenetics Chromosomal aberrations	Negative ± S9 for clastogenic/aneugenic activity up to cytotoxic and precipitating 200 μg/mL
870.5395	Cytogenetics Micronucleus test on mouse	Negative up to the highest dose tested (limit dose) 2,000 mg/kg
870.5500	Other Effects Bacterial DNA repair test (Rec-assay)	Negative ± S9 up to limit of solubility at 8,000 μg/disc
870.7485	Metabolism and pharmacokinetics in rats	There was rapid absorption (irrespective of dose t_{cmax} = 0.25–0.5 hrs) and rapid elimination at the low dose ($t_{\frac{1}{2}}$ 4.4–5.8 hrs) while there was saturated absorption with prolonged elimination ($t_{\frac{1}{2}}$ of 7.6–11.6 hrs) at the high-dose. The extent of absorption (as per cent of administered dose) was highly dose-dependent being nearly 75% at the low dose and only about 5% at the high dose. Both the urine and feces were major routes of excretion at the low dose with most of the urinary radioactivity being a metabolite named CCBA (4-(4-chloro-2-cyanoimidazol-5-yl)benzoic acid). The biliary elimination was highly variable at the low dose (~12–39% of the administered low dose) and negligible (<2%) in the high-dose groups. Urinary or biliary excretion in the high-dose groups was low (each ~2%) with most of the radioactivity being CCBA. Irrespective of the dosing regimen, most of the recovered fecal radioactivity was unchanged parent compound; the major fecal metabolites were CCBA and 4-chloro-5-p-tolylimidazole-2-carbonitrile (CCIM) each of which being less than 5% of the administered dose. Tissue burdens at $t_{\frac{1}{2}}$, t_{max}, and at 168 hours post dose indicated rapid clearance and low tissue burdens suggesting little or no bioaccumulation or sequestration.

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 intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 cyazofamid used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYAZOFAMID

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 100 mg/kg UF = 100 Acute RfD = 1.0 mg/kg	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 1.0 mg/kg	Rat Prenatal Developmental Toxicity (MRID 45408933) LOAEL = 1,000 mg/kg based on developmental toxicity findings of increased incidence of bent ribs.
Acute Dietary (General population including infants and children)	NOAEL = NA UF = NA Acute RfD = NA	FQPA SF = NA aPAD = acute RfD ÷ FQPA SF = NA	Not Required. No adverse effects were observed which could be attributed to a single-dose exposure.
Chronic Dietary (All populations)	NOAEL= 94.8 mg/kg/day UF = 100 Chronic RfD = 0.95 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.95 mg/kg/day	18–Month Mouse Oral Carcinogenicity (MRID 45408932) LOAEL = 985 mg/kg/day based on increased skin lesions.
Short- (1–30 days) and Intermediate-Term (1 to 6 months) Incidental Oral	NOAEL= NA No Residential Uses	Residential LOC for MOE = NA Occupational = NA	NA
Short- (1–30 days) and Intermediate-Term (1 to 6 months) Dermal	Oral study NOAEL = 100 mg/kg/day (dermal absorption rate = 37%)	Residential LOC for MOE = NA Occupational LOC for MOE = 100	Rat Prenatal Developmental Toxicity (MRID 45408933) LOAEL = 1,000 mg/kg based on developmental toxicity findings of increased incidence of bent ribs.
Long-Term Dermal (>6 months)	Oral study NOAEL = 94.8 mg/kg/day (dermal absorption rate = 37%)	Residential LOC for MOE = NA Occupational LOC for MOE = 100	18–Month Mouse Oral Carcinogenicity (MRID 45408932) LOAEL = 985 mg/kg/day based on increased skin lesions.
Short- (1–30 days) and Intermediate-Term (1 to 6 months) Inhalation	Oral study NOAEL = 100 mg/kg/day	Residential LOC for MOE = NA Occupational LOC for MOE = 100	Rat Prenatal Developmental Toxicity (MRID 45408933) LOAEL = 1,000 mg/kg based on developmental toxicity findings of increased incidence of bent ribs.
Long-Term Inhalation (>6 months)	Oral study NOAEL = 94.8 mg/kg/day	Residential LOC for MOE = NA Occupational LOC for MOE = 100	18–Month Mouse Oral Carcinogenicity (MRID 45408932) LOAEL = 985 mg/kg/day based on increased skin lesions.
Cancer (oral, dermal, inhalation)	Not Applicable	NA	NA

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Permanent and temporary tolerances for residues of cyazofamid and its metabolites are not currently established. Risk assessments were conducted by EPA to assess dietary exposures from the proposed uses of cyazofamid on food and feed crops 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 1–day or single exposure.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) and Lifeline™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: As an acute dietary endpoint was not identified for the general population including infants and children, the acute dietary analysis was performed for the population subgroup females 13 to 49 years old only. The assumptions of this dietary exposure assessment are tolerance level residues and 100% crop-treated.

At the 95th percentile of exposure, the Tier 1 acute DEEM-FCID™ and Lifeline™ analysis gave the results listed in Table 3. For the acute analysis, the exposure at the 95th percentile for Females 13 to 49 years old is 0.003769 mg/kg/day for DEEM-FCID™ or

0.004013 mg/kg/day for LifelineT, which utilizes <1% of the acute PAD for cyazofamid for both DEEM-FCID™ and Lifeline™. The results of the Lifeline™ and DEEM-FCID™ analyses are fully consistent.

A summary of the acute dietary exposure estimates for cyazofamid and its metabolote CCIM used for human risk assessment are shown in Table 3 of this unit:

TABLE 3.—ACUTE DIETARY EXPOSURE ESTIMATES FOR CYAZOFAMID

Population Subgroup	aPAD (mg/kg/day)	DEEM-FCID™		LifeLineTM	
		Exposure (mg/kg/day)	%aPAD[1]	Exposure (mg/kg/day)	%aPAD[1]
Females 13–49 years old	1.0	0.003769	<1	0.004013	<1

[1] Percent Acute PAD = (Exposure ÷ Acute PAD) x 100%.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™ and Lifeline™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The assumptions of this dietary exposure assessment are tolerance level residues and 100% crop-treated.

The Tier 1 chronic DEEM-FCID™ and Lifeline™ analysis gave the results listed in Table 4. For the chronic analysis, the most highly exposed population subgroup and the highest risk estimate was for Children 1 to 2 years old. The chronic exposures for Children 1 to 2 years old are 0.004778 mg/kg/day for DEEM-FCID™) or 0.004529 mg/kg/day for Lifeline™), which utilize <1.0% (for both DEEM-FCID™ and Lifeline ™) of the chronic PAD for cyazofamid. The results of the Lifeline™ and DEEM-FCID™ analyses are fully consistent.

A summary of the chronic dietary exposure estimates for cyazofamid used for human risk assessment is shown in Table 4 of this unit:

TABLE 4.—CHRONIC DIETARY EXPOSURE ESTIMATES FOR CYAZOFAMID

Population Subgroup	cPAD (mg/kg/day)	DEEM-FCID™		LifeLine™	
		Exposure (mg/kg/day)	%cPAD[1]	Exposure (mg/kg/day)	%cPAD[1]
General U.S. Population	0.95	0.001016	<1	0.000988	<1
All Infants (<1 year old)	0.95	0.001448	<1	0.001501	<1
Children 1–2 years old	0.95	0.004778	<1	0.004529	<1
Children 3–5 years old	0.95	0.003101	<1	0.003236	<1
Children 6–12 years old	0.95	0.001338	<1	0.00131	<1
Youth 13–19 years old	0.95	0.000567	<1	0.000589	<1
Adults 20–49 years old	0.95	0.000684	<1	0.000751	<1
Adults 50+ years old	0.95	0.000774	<1	0.000802	<1
Females 13–49 years old	0.95	0.000720	<1	0.000816	<1

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

iii. *Cancer*. A cancer dietary assessment was not conducted because cyazofamid has been classified as ''not likely to be carcinogenic to humans''.

iv. *Anticipated residue and percent crop treated (PCT) information*. The Agency did not use anticicated residue estimates and PCT information in the cyazofamid dietary exposure assessment.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for cyazofamid and its metabolites 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 cyazofamid.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Groudwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. 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. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a percent of the reference dose (%RfD) or percent of the population adjusted dose (%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.

Based on the FIRST and SCI-GROW models, the EECs of cyazofamid and its metabolites for acute exposures are estimated to be 6.436 parts per billion (ppb) for surface water and 0.002680 ppb for ground water. The EECs for chronic exposure is estimated to be 0.495 ppb for surface 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). Cyazofamid is not registered for use on any sites that would result in residential exposure.

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 cyazofamid and any other substances and cyazofamid 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 cyazofamid 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 policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site 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 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 based on reliable data 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There are no concernsor residual uncertainties for pre- and or postnatal toxicity.

3. *Conclusion*. EPA determined that the 10X safety factor to protect infants and children should be removed *i.e.*, reduced to 1X. The FQPA factor is removed because:

i. In the prenatal developmental toxicity study in rabbits, there was no indication of increased susceptibility (qualitative or quantitative) of rabbit fetuses to *in utero* exposure to cyazofamid. No maternal or developmental effects were seen at any dose up to the limit dose of 1,000 mg/kg/day.

ii. In the prenatal developmental toxicity study in rabbits, there was no indication of increased susceptibility (qualitative or quantitative) of rabbit fetuses to *in utero* exposure to cyazofamid. No maternal or developmental effects were seen at any dose up to the limit dose of 1,000 mg/kg/day.

iii. In the two-generation reproduction study, the highest dose tested (>1,000 mg/kg/day) did not cause maternal systemic toxicity nor did it elicit reproductive or offspring toxicity.

iv. The Agency concluded that the concern is low for the quantitative susceptibility seen in the rat developmental toxicity study and there are no residual uncertainties because:

a. The developmental effect is well identified with clear NOAEL/LOAEL.

b. The developmental effect (increased bent ribs) is a variation rather than a malformation.

c. The developmental effect is seen only at the limit dose of 1,000 mg/kg/day.

d. This endpoint is used to establish the acute RfD for Females 13–49 years old.

e. The overall toxicity profile indicates that cyazofamid is not a very toxic compound.

v. There were no indications of pre- or postnatal toxicity and no residual uncertainties from the rabbit developmental study or the rat two generation reproduction study.

vi. The exposure assessments are Tier 1, conservative, high-end assessments and will not underestimate the potential dietary (food and water) exposures.

vii. There are no proposed residential uses.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking 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 residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (*i.e.*, the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default

body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to cyazofamid will occupy <1% of the aPAD for females 13 years and older. In addition, there is potential for acute dietary exposure to cyazofamid in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CYAZOFAMID

Population Subgroup	aPAD (mg/kg/day)	Acute 95% Food Exposure[1] (mg/kg/day)	Maximum Acute Water Exposure[2] (mg/kg/day)	Ground Water EDWC[3] (ppb or µg/L)	Surface Water EDWC[3] (ppb or µg/L)	Acute DWLOC[4] (ppb or µg/L)
Females 13–49 years old	1.0	0.004013	1.0	0.495	6.436	3.0×10^4

[1] The exposure from the model producing the highest exposure estimate for the population subgroup was used.
[2] Maximum Water Exposure (mg/kg/day) = aPAD (mg/kg/day) - Dietary (Food) Exposure.
[3] The highest level was used.
[4] DWLOC(µg/L) = [maximum water exposure (mg/kg/day) x body weight (kg)] [water consumption (L) x 10^{-3} mg/µg]. A body weight of 70 kg is assumed for adults, 60 kg for females and youth, and 10 kg for children; water consumption is assumed to be 2 L for adults and 1 L for children.

2. *Chronic risk*. The chronic dietary exposure analyses in this assessment for cyazofamid result in dietary risk (food only) estimates that are below the Agency's level of concern for chronic dietary (food only) exposure. For the chronic analysis, the most highly exposed population subgroup and the highest risk estimate was for children 1 to 2 years old. The chronic exposures for children 1 to 2 years old are 0.004778 mg/kg/day for DEEM-FCID™ or 0.004529 mg/kg/day for Lifeline™, which utilize <1.0% (for both DEEM-FCID™ and Lifeline™) of the chronic PAD for cyazofamid. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 6 of this unit:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CYAZOFAMID

Population Subgroup	cPAD (mg/kg/day)	Chronic Food Exposure[1] (mg/kg/day)	Maximum Chronic Water Exposure[2] (mg/kg/day)	Ground Water EDWC[3] (ppb or µg/L)	Surface Water EDWC[3] (ppb or µg/L)	Chronic DWLOC[4] (ppb or µg/L)
General U.S. Population	0.95	0.001016	0.95	NA	NA	3.3×10^4
All Infants (<1 year old)	0.95	0.001501	0.95	NA	NA	9.5×10^3
Children 1–2 years old	0.95	0.004778	0.95	NA	NA	9.5×10^3
Children 3–5 years old	0.95	0.003236	0.95	NA	NA	9.5×10^3
Children 6–12 years old	0.95	0.001338	0.95	0.495	8.085	9.5×10^3
Youth 13–19 years old	0.95	0.000589	0.95	NA	NA	2.8×10^4
Adults 20–49 years old	0.95	0.000751	0.95	NA	NA	3.3×10^4
Adults 50+ years old	0.95	0.000802	0.95	NA	NA	3.3×10^4
Females 13–49 years old	0.95	0.000816	0.95	NA	NA	2.8×10^4

[1] The exposure from the model producing the highest exposure estimate for the population subgroup was used.
[2] Maximum Water Exposure (mg/kg/day) = cPAD (mg/kg/day) - Dietary (Food) Exposure
[3] The highest level was used.
[4] DWLOC(µg/L) = [maximum water exposure (mg/kg/day) x body weight (kg)] [water consumption (L) x 10^{-3} mg/µg]. A body weight of 70 kg is assumed for adults, 60 kg for females and youth, and 10 kg for children; water consumption is assumed to be 2L for adults and 1L for children.

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

Cyazofamid is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

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

Cyazofamid is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency classified cyazofamid as ''not likely to be carcinogenic to humans.'' Thus, cyazofamid is not expected to pose a risk.

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 cyazofamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The Food and Drug Administration's (FDA's) Multi-Residue Protocol D (without cleanup) is the acceptable enforcement method in crops. The petitioner should provide the Agency with a single modified method for all crops with the inclusion of the minor variations for crops as needed.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican MRL's or tolerances for cyazofamid on cucurbits, tomato, potato, and wine. Therefore, international harmonization is not an issue for this petition.

C. Conditions

The following confirmatory data are needed for wheat. Data are listed below by guideline series.

1. *Harmonized guideline 860.1300—Nature of the residue.* The metabolism studies conducted on plants (grapes, potatoes, and tomatoes) and livestock (goats and hen) as well as the confined rotational crop study are deemed tentatively acceptable. To fully upgrade each study, the petitioner is required to provide information pertaining to dates of sample collection, extraction, and final analysis. This information is required for each study to determine actual sample storage intervals.

The metabolic profiles in crop matrices (grape, wine; potato and tomato) determined at the beginning and at the end of the analytical phase were not provided. Representative chromatograms of the radiolabeled residues taken before and after storage under frozen conditions should be submitted. In the future, additional metabolism data might be required if uses on additional crops are requested.

2. *Harmonized guideline 860.1340—Residue analytical methods.* The petitioner has provided the proposed enforcement method entitled, ''Analytical Method for IKF–916 and CCIM in Tomato Samples'' as an attachment to the ILV of the method. The Agency finds that the Residue Analytical Methods used for data collection may be used as a single analyte confirmatory method. However, the petitioner should provide the Agency with a single modified method for all crops with the inclusion of the minor variations for crops as needed. The FDA's Multi-Residue Protocol D (without cleanup) is the acceptable enforcement method in crops.

3. *Harmonized guideline 860.1380—Storage stability.* Storage stability data for 18 months on the representative commodities of the cucurbit group should be submitted to support the storage intervals and conditions of the crop field trials.

4. *Harmonized guideline 860.1850—Confined Accumulation in rotational Crops.* The submitted study is tentatively deemed adequate to satisfy data requirements for a confined rotational crop study pending submission of information pertaining to extraction and analysis dates of samples from the 31–day PBI. These dates are required to determine the actual sample storage intervals and need for additional storage stability data. The supporting storage stability data from the current submission indicate that the parent and its metabolites CCIM and CCBA are relatively stable in fortified samples of carrot roots, lettuce, and wheat forage stored frozen for up to 4 months. The identities of the parent, CCIM, CCIM-AM, and sugars are deemed adequately identified pending submission of representative TLC or data from TLC analyses.

5. *Other data.* Historical control data for dog toxicity studies.

V. Conclusion

Therefore, tolerances are established for the combined residues of cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide, and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, expressed as cyazofamid, in or on cucurbit vegetables (Group 9) at 0.10 ppm, potato at 0.02 ppm, tomato at 0.20 ppm, and grape, wine at 1.5 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP–2004–0211 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 29, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th Street, NW., Suite 350, Washington, DC. 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) 564–6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0211 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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. 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 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 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. 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 section 408(n)(4) of FFDCA. 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. 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 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:_____

_____

Director, 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 180.601 is added to read as follows:

§ 180.601 Cyazofamid; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide, and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, expressed as cyazofamid, in or on the following commodities:

Commodity	Parts per million
Cucurbit vegetables (Group 9)	0.10
Grape, wine,* import	1.5
Potato	0.02
Tomato	0.20

*No domestic registrations.

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

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

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

[FR Doc. 04–21931 Filed 9–29–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0298; FRL–7678–7]

Octanal; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of octanal on growing crops or raw agricultural commodities (RAC) when used as an inert ingredient in pesticide formulations applied to growing crops, RAC after harvest, or to animals. Firmenich submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of octanal.

DATES: This regulation is effective September 30, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0298. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8033; e-mail address: *campbell.princess@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:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)* you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/.*

II. Background and Statutory Findings

In the **Federal Register** of December 20, 2000 (65 FR 79834) (FRL–6751–9), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (6E4757) by Firmenich, P.O. 5880, Princeton, NJ 08543.

Firmenich requested that octanal, also known as caprylic aldehyde, or 1-octanal, be approved for use as an inert ingredient in pesticide formulations applied to growing crops, RACs after harvest, or to animals at an amount that was not to exceed 0.2% of the formulated product. This notice included a summary of the petition prepared by the petitioner Firmenich.

The petition requested that 40 CFR 180.1001, (c) and (e), newly re-designated as § 180.910 and § 180.930 April 28, 2004 (69 FR 23113) (FRL–7335–4), be amended by establishing an exemption from the requirement of a tolerance for residues of octanal, (CAS Registration No. 124–13–0). There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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