Note: This document was received at the Office of the Federal Register on October 13, 2004.

Dated: January 12, 2004.

S. A. Kenney,

Commander, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law).

[FR Doc. 04–23215 Filed 10–19–04; 8:45 am]

BILLING CODE 3510–FF–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0327; FRL–7682–1]

Cyprodinil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on almond, hulls; bean, dry; bean, succulent; and leafy greens subgroup 4A, except spinach. Interregional Research Project Number 4 (IR–4) 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 October 20, 2004. Objections and requests for hearings must be received on or before December 20, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0327. 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 South 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: Maria I. Rodriguez, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6710; e-mail address: *rodriguez.maria@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/*.

II. Background and Statutory Findings

In the **Federal Register** of April 21, 2003 (68 FR 19528) (FRL–7301–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6530; note that this PP was inadvertently reported as PP 2E6530 in the unit entitled **Summary of Petition** of that notice) by IR–4, 681 U.S. Highway #1 South, New Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.532 be amended by establishing tolerances for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on almond, hulls at 8.0 parts per million (ppm). That notice included a summary of the petition prepared by IR–4, the registrant. There were no comments received in response to the notice of filing.

In the **Federal Register** of September 1, 2004 (69 FR 53436) (FRL–7676–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 3E6638 and PP 3E6700) by IR–4, 681 U.S. Highway #1 South, New Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.532 be amended by establishing a tolerance for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on leafy greens subgroup 4A, except spinach at 30 ppm (PP 3E6638); bean, dry and bean, succulent at 0.6 ppm each (PP 3E6700). That notice included a summary of the petition prepared by IR–4, the registrant. Comments were received from one individual in New Jersey opposing and objecting the establishment of tolerances for residues of cyprodinil. The individual criticized IR–4's involvement in the pesticide registration as well as EPA's way of conducting pesticide registration. EPA's response to the public comments received is in Unit V. of this document.

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

aggregate exposure to the pesticide chemical residue....''

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 tolerances for residues of cyprodinil in or on almond, hulls at 8.0 ppm; bean, dry and bean, succulent at 0.6 ppm each; and leafy greens subgroup 4A, except spinach at 30 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 cyprodinil as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of September 19, 2003 (68 FR 54808) (FRL–7326–4).

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 cyprodinil used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 19, 2003 (68 FR Page 54808) (FRL–7326–4).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.532) for the residues of cyprodinil, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from cyprodinil 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.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (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: An unrefined, Tier 1 acute dietary exposure assessment (using tolerance-level residues, DEEM default processing factors and assuming 100% crop treated for all proposed commodities) was conducted for the females 13–49 years old population subgroup.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: An unrefined, Tier 1 chronic dietary

exposure assessment (using tolerance-level residues, DEEM default processing factors, and assuming 100% crop treated for all proposed commodities) was conducted for the general U.S. population and various population subgroups.

iii. *Cancer*. A quantitative cancer aggregate-exposure assessment was not performed because cyprodinil is not carcinogenic.

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

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 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 %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 cyprodinil they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of cyprodinil for acute exposures are estimated to be 73 parts per billion (ppb) for surface water and 0.062 ppb for ground water. The EECs for chronic exposures are estimated to be 61 ppb for surface water and 0.062 ppb for ground 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).

Cyprodinil 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 cyprodinil and any other substances and cyprodinil 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 cyprodinil 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 concerns or uncertainties for pre- and/or post-natal exposure.

3. *Conclusion*. There is a complete toxicity data base for cyprodinil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The 10X default safety factor (SF) to protect infants and children has been reduced to 1X. The basis for the recommendation has been discussed in Unit III.D. of the final rule published in the **Federal Register** of September 19, 2003 (68 FR 54808) (FRL–7326–4).

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 cyprodinil will occupy, 4% of the aPAD of 1.5 mg/kg/day for females 13 to 49 years. For the general population, no toxic effects of concern that could be attributed to a single exposure were observed in the oral toxicity studies, including the developmental toxicity studies in rats and rabbits. Therefore, cyprodinil is not expected to pose an acute risk to this population subgroup. In addition, there is potential for acute dietary exposure to cyprodinil 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 1. of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CYPRODINIL

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13–49 years old)	1.5	4	73	0.062	43,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyprodinil from food will utilize 38% of the cPAD of 0.03 mg/kg/day for the U.S. population, and 67% of the cPAD for the most highly exposed population subgroup, children 1–2 years old. There are no residential uses for cyprodinil that result in chronic residential exposure to cyprodinil. In addition, there is potential for chronic dietary exposure to cyprodinil 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 cPAD, as shown in Table 2. of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CYPRODINIL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.03	38	61	0.062	650
Children (1–2 years old)	0.03	67	61	0.062	100

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).

Cyprodinil 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).

Cyprodinil 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*. Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential, cyprodinil was classified as ''not likely to be carcinogenic to humans.'' Therefore, cyprodinil is not expected to pose a cancer risk to humans.

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 cyprodinil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Head and leaf lettuce, lima bean, dry bean, and snap bean were analyzed using Novartis working method AG–631B. The method uses High Performance Liquid Chromatography (HPLC) with Column Switching. Almonds were analyzed using Syngenta tolerance enforcement method AG–631A. The method uses HPLC with Column Switching, with modifications. The confirmatory method uses HPLC with Ultraviolet detection (HPLC/UV). The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits (MRLs)

for residues of cyprodinil in/on the proposed crops. Therefore, harmonization is not an issue.

V. EPA's Response to Public Comments Received Regarding the Notice of Filing

Comments were received from one individual in New Jersey opposing and objecting the establishment of tolerances for residues of cyprodinil. The individual criticized IR–4's involvement in the pesticide registration as well as EPA's way of conducting pesticide registration. The comments were in response to the notice of filing published in the **Federal Register** of September 1, 2004 (69 FR 53436) (FRL–7676–4).

One comment indicated that IR–4 and Rutgers University are profiteering by registering pesticides for Syngenta. The IR–4 program was created by Congress in 1963 in order to assist minor crop growers in the process of obtaining pesticide registrations. IR–4 National Coordinating Headquarters is located at Rutgers University in New Jersey and receives the majority (90%) of its funding from the USDA. It is the only publicly funded program that conducts research and submits petitions for tolerances. IR–4 operates in collaboration with USDA, the Land Grant University System, the agrochemical industry, commodity associations, and EPA. IR–4 identifies needs, prioritizes accordingly, and conducts research. The majority (over 80%) of IR–4's research is conducted on reduced-risk chemicals. Under the Pesticide Registration Improvement Act (PRIA), IR–4 works in cooperation with the registrant to request a waiver for the registration services. The waiver may be granted if the application is solely associated by simultaneous submission with a tolerance petition in connection with IR–4 and if it is in the public interest. This fee waiver serves as an incentive to pursue registration of minor uses supported by the IR–4 program. In addition to the work done in pesticide registration, IR–4 develops risk mitigation measures for existing registered products. Therefore, IR–4 and Rutgers University are not profiteering from registering pesticides.

Another comment alleged that according to information on the fifth page of the notice of filing, there is no data at EPA to support the pesticide registration. The comment applies to the use of ''available data'' concerning the cumulative effects of the pesticide's residues and ''other substances that have a common mechanism of toxicity.'' In this case, EPA did not assume that this chemical has a common mechanism of toxicity with other substances as the chemical does not generate metabolites produced also by other chemicals. For specific information regarding EPA's approach to the use of common mechanism of toxicity to evaluate the cumulative effects of chemicals, please refer to EPA's website at *http://www.epa.gov/pesticides/cumulative/* to see policy statements.

An additional comment indicated that during animal testing, rabbits are abused, tortured, and fed toxic chemicals. EPA test guidelines recommend rabbits as test animals in acute eye irritation studies as well as in longer term studies such as developmental toxicity and reproduction studies. Results obtained from studies conducted with animals (in general) are relevant to humans because cells and molecules of humans can be very similar to those of animals. Therefore, if a pesticide causes toxicity in animals, it is likely to do so in humans as well. EPA supports the use of the least possible number of animals in the pertinent studies. In addition, it should be noted that currently there are no *in vitro* studies that can address the concerns these studies satisfy. EPA is working with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to investigate *in vitro* methods to determine the toxicological concerns associated with the use of pesticides.

VI. Conclusion

Therefore, the tolerances are established for residues of cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on almond, hulls at 8.0 ppm; bean, dry and bean, succulent at 0.6 ppm each; and leafy greens subgroup 4A, except spinach at 30 ppm.

VII. 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–2004–0327 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 December 20, 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 St., NW., Washington, DC 20005. 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 VII.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–2004–0327, 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).

VIII. 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.

IX. 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: October 6, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 180.532 is amended as follows:

■ a. By revising the commodity ''Almond, hulls'' in the table in paragraph (a).

■ b. By alphabetically adding commodities to the table in paragraph (a).

§ 180.532 Cyprodinil; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond, hulls	8.0
* * *	* *
Bean, dry	0.6
Bean, succulent	0.6
* * *	* *
Leafy greens subgroup 4A, except spinach	30
* * *	* *

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[FR Doc. 04–23261 Filed 10–19–04; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 310

[Docket Number: MARAD–2004–19397]

RIN 2133–AB61

Amended Service Obligation Reporting Requirements for State Maritime Academy Graduates

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Interim final rule with request for comments.

SUMMARY: In this interim final rule, the Maritime Administration (MARAD, we, us, or our) will change the service obligation reporting requirements for State maritime academy graduates who receive Student Incentive Payments (SIPs). The new reporting requirements create standard reporting dates that coincide with the U.S. Naval Reserve/Merchant Marine Reserve (USNR/MMR) service reporting dates. This rulemaking also provides for the electronic submission of reports as the primary means of submission to MARAD.

DATES: This interim final rule is effective October 20, 2004. However, MARAD will consider comments received not later than November 19, 2004.

ADDRESSES: You may submit comments (identified by DOT DMS Docket Number MARAD–2004–19397) by any of the following methods:

- Web site: *http://dms.dot.gov*. Follow the instructions for submitting comments on the DOT electronic docket site.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 7th St., SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 7th St., SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number for this rulemaking. Note that all comments received will be posted without change to *http://dms.dot.gov* including any personal information provided. Please see the Privacy Act heading under Regulatory Notices.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 7th St., SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Rita Jackson, Academies Program Officer, Office of Policy and Plans, Maritime Administration, Department of Transportation, 400 7th St., SW., Room 7123, Washington, DC 20590, telephone: (202) 366–0284.

SUPPLEMENTARY INFORMATION: The Student Incentive Payment Program provides financial assistance to certain eligible State maritime academy students to help offset educational costs. Students who receive Student Incentive Payments must sign service obligation contracts that obligate the students to certain post-graduate service obligation requirements. The requirements include: (1) Serving for three (3) years after graduation in the foreign or domestic commerce or the national defense of the United States in maritime-related employment; (2) maintaining a valid license as an officer in the merchant marine of the United States for at least six (6) years following the date of graduation, accompanied by the appropriate national and international endorsements and certification as required by the United States Coast Guard for service aboard vessels on domestic and international voyages, and (3) accepting if tendered an appointment as, and serving as a commissioned officer in the United States Naval Reserve, the United States Coast Guard Reserve, or any other reserve unit of an armed force of the United States for six (6) years following graduation. The above requirements are set forth in 46 U.S.C. 1295c(g)(3)(C), (D), and (E). In addition to the above service obligations, graduates are required, under 46 U.S.C. 1295c(g)(3)(F), to submit reports to MARAD indicating compliance with their service obligations.

Under the current regulations at 46 CFR 310.7(b)(6)(i), State maritime academy SIP graduates are required to submit their service obligation reports thirteen (13) months following graduation and each succeeding twelve (12) months for a total of three (3) years. The three (3) year reporting period, however, does not accurately reflect the requirement in 46 U.S.C. 1295c(g)(3)(F) that graduates report compliance with all of their service obligations, because graduates must submit reports indicating their compliance not only with the three (3) year service (*i.e.*, employment) requirement, but also with the six (6) year licensing and reserve components of the service obligation. Thus, under the law, graduates must submit compliance reports for a minimum of six (6) years to account for all of their service obligations. The six (6) year reporting requirement dates back to the Maritime Education and Training Act of 1980 (Pub. L. 96–453) but has not been reflected in MARAD's regulations. However, as a matter of agency practice, MARAD has long required graduates to submit reports for six (6) years to report compliance with their service obligation requirements.

In this interim final rule, MARAD is amending its regulations to reflect the requirement that graduates report for six (6) years (or until all components of the service obligation are fulfilled, whichever is latest). In addition, MARAD is amending the service obligation reporting requirements to require each graduate to file a report between January 1 and March 1 following graduation and during the same January 1 to March 1 time frame for a minimum of six (6) years thereafter.

The new reporting dates coincide with the USNR/MMR's service reporting dates to create a standard reporting period. This standardized reporting period should make reporting less burdensome because graduates will be able to compile and submit information to MARAD and to the USNR during the same time frame each year.

This rulemaking will also provide for the electronic submission of reports as the primary means of submission. Graduates must submit annually the Maritime Administration Service Obligation Compliance Report and Merchant Marine Reserve, U.S. Naval Reserve (USNR), Annual Report (Form MA–930). Graduates may submit their Service Obligation Compliance Reports electronically via the Maritime Service