List of Subjects in 40 CFR Part 180

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

Dated: February 4, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
1,4-Benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol, adipic acid, and hexamethylene diisocyanate, minimum number average molecular weight (in amu) 30,000 (CAS Reg. No. 55231–08–8).	For use in honeybee hive miticide formulations.	Component of controlled release agent.
* * *	* *	* *

[FR Doc. 2011–3111 Filed 2–10–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0982; FRL–8859–6]

Fludioxonil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fludioxonil in or on pineapple. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on pineapple. This regulation establishes a maximum permissible level for residues of fludioxonil in or on this commodity. The time-limited tolerance expires on December 31, 2013.

DATES: This regulation is effective February 11, 2011. Objections and requests for hearings must be received on or before April 12, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see also* Unit I.C. of the **SUPPLEMENTARY INFORMATION** section).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0982. All documents in the docket are listed in the docket index available in *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 308–9356; *e-mail address: conrath.andrea@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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 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 get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0982 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 12, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0982, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for residues of fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile), in or on pineapple at 13 parts per million (ppm). This time-limited tolerance expires on December 31, 2013.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.,* without having received any petition from an outside party.

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. * * *"

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Fludioxonil on Pineapple and FFDCA Tolerances

The applicant stated that unforeseen changes in available options for shipping Hawaiian pineapple to the mainland of the United States resulted in increased storage and transport time for the fruit. The overall increased shipment time is allowing surface molds to become established, which is leading to rejection, downgrading, or dumping of the unacceptable fruit. The Applicant stated that because of this unanticipated situation, an emergency situation exists, with significant economic losses suffered. Further, the Applicant asserts that without a suitable fungicide, such as fludioxonil, to address this issue, the future viability of the pineapple industry in Hawaii is threatened.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of fludioxonil on Hawaiian pineapple for control of surface molds.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of fludioxonil in or on pineapple. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this time-limited tolerance expires on December 31, 2013, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on pineapple after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether fludioxonil meets FIFRA's registration requirements for use on pineapple or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of fludioxonil by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than Hawaii to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for fludioxonil, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with the factors specified in 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 expected as a result of this emergency exemption request and the time-limited tolerance for residues of fludioxonil on pineapple at

13 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance follows.

A. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the level at which no adverse effects are observed (the NOAEL) and the lowest level at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, *see http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for fludioxonil used for human risk assessment can be found at *http://www.regulations.gov* in document "Fludioxonil. Human Health Risk assessment for a Section 18 Emergency Tolerance on Pineapple," dated August 4, 2010, p. 23–24 in Docket ID number EPA–HQ–OPP–2010–0982.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fludioxonil, EPA considered exposure under the time-limited tolerance established by this action as well as all existing fludioxonil tolerances in 40 CFR 180.516. EPA assessed dietary exposures from fludioxonil in food as follows:

i. *Acute exposure.* Adverse effects from acute exposure were identified for fludioxonil for the population subgroup females 13–49 years old. The acute population adjusted dose (aPAD) is set at 1.0 milligrams/kilograms/day (mg/kg/day) based upon acute effects of increased incidence of fetuses and litters with dilated renal pelvis and dilated ureter seen in the rat developmental study. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted an acute dietary assessment assuming established and proposed tolerance-level residues for all commodities and default 100 percent crop treated (PCT) information for the population subgroup females 13–49 years old. No anticipated residue or estimated PCT data were used. The estimated peak drinking water concentration of 108 parts per billion (ppb) was directly incorporated into the acute risk assessment. There were no significant toxicological effects attributable to a single exposure (dose) for the general population or any other population subgroups; therefore these populations' subgroups were not included in this assessment. For food and drinking water, the exposure to females 13–49 years old (the only population subgroup demonstrating acute effects) utilized 15% of the aPAD at the 95th percentile of exposure distribution.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA conducted a chronic dietary assessment assuming established and proposed tolerance-level residues with the exception of the following: Anticipated residues (ARs) were generated for apple, grapefruit, lemon, lime, orange, pear, tomato, lettuce (head and leaf), fresh parsley, *Brassica* leafy vegetables (crop group 5), grape, cherry, peach, and plum based upon field trial data. Empirical processing factors were determined from processing studies for the juices of tomato, apple, grapefruit, lemon, lime, grape, and orange, and for raisins; default processing factors were used in all other instances. No PCT data were used (100% crop treated was assumed). The estimated chronic drinking water concentration of 53 ppb was directly incorporated into the assessment. Food and water consumption were compared to the chronic population adjusted dose (cPAD) of 0.03 mg/kg/day, which is based upon the chronic effect of decreased weight gain in females seen in the 1-year dog feeding study. For food and water consumption, the chronic exposure to fludioxonil utilized 26% of the cPAD for the general U.S. population and 88% of the cPAD for children 1–2 years old, the most highly exposed population subgroup.

iii. *Cancer.* Based on the available data, EPA has determined that fludioxonil is a "Group D" chemical, not classifiable as to human carcinogenicity, and poses a negligible cancer risk. Cancer studies with fludioxonil only showed marginal evidence of cancer in one sex of one species. There was no evidence of carcinogenicity in mice when tested up to the highest dose of 7,000 ppm. There was no evidence of carcinogenicity in male rats, but there was a statistically significant increase, both trend and pairwise, of combined hepatocellular tumors in female rats. The pairwise increase for combined tumors was statistically significant, but only at p=0.03, which is not a strong indication of a positive effect. Further, statistical significance was only found when liver adenomas were combined with liver carcinomas. Finally, the increase in these tumors was within, but at the high end, of the historical controls. Fludioxonil was not mutagenic in the tests for gene mutations. However, based on the induction of polyploidy in the *in vitro* Chinese hamster ovary cell cytogenetic assay and the suggestive evidence of micronuclei induction in rat hepatocytes *in vivo,* additional mutagenicity testing was performed in three studies specifically designed to address the concerns regarding aneuploidy. The results of these assays were negative for aneuploidy activity. Therefore, the Agency concluded that a dietary exposure assessment for assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use PCT information in the dietary assessment for fludioxonil. One hundred percent of the pineapple crop was assumed treated.

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

Anticipated residue data were used in the chronic (non-cancer) dietary risk analyses but not in the acute dietary risk analysis. For certain tolerances, the anticipated residue values were determined from the field trial studies. Additionally, results of processed commodities studies show that fludioxonil residues do not concentrate to the extent that the existing crop tolerances would be exceeded.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fludioxonil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fludioxonil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of fludioxonil for acute exposures are estimated to be 108 ppb for surface water and 0.4 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 53 ppb for surface water and 0.4 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure models. For acute dietary risk assessment, the water concentration value of 108 ppb was used to assess the contribution of fludioxonil from drinking water. For chronic dietary risk assessment, the water concentration of value 53 ppb was used to assess the contribution of fludioxonil from drinking water.

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

Fludioxonil is currently registered for the following uses that could result in residential exposures: Residential turf and ornamental use, restricted to commercial applicators only. EPA assessed residential exposure using the following assumptions: The use on pineapple discussed in this document does not result in any residential non-occupational exposures. Since there are no short- or intermediate-term dermal toxicity endpoints for fludioxonil, only a toddler post-application assessment for incidental ingestion exposures to treated lawns was conducted (for all child/infant subgroups). The combined short-term oral exposure risk estimate, which includes hand-to-mouth, object-to-mouth and soil ingestion pathways, was determined to be 0.013 mg/kg bw/day, while the intermediate-term was determined to be 0.0074 milligrams/kilograms of bodyweight/day (mg/kg bw/day). It should be noted that each of the incidental oral assessments (*i.e.,* hand-to-mouth, object-to-mouth and soil ingestion) are considered conservative. Therefore, combining all the assessments is expected to provide a highly conservative assessment of children's incidental oral exposure.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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."

EPA has not found fludioxonil to share a common mechanism of toxicity with any other substances, and fludioxonil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fludioxonil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, *see* EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA, as modified by the Food Quality Protection Act (FQPA), provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure of rats and rabbits or following prenatal/postnatal exposure of rats. In the developmental study in rats, there was an increase in the number of fetuses and litters with dilated renal pelvis and dilated ureter, as well as a reduction in maternal body weight gain, at the lowest observed adverse effect level. The developmental effect was considered to be related to maternal toxicity rather than an indication of increased susceptibility. Since the developmental effects occurred at the same exposure levels that caused maternal effects, no evidence of increased susceptibility in rats was demonstrated from the developmental study. In the 2-generation rat reproduction study, offspring toxicity was seen at the dose that produced parental (maternal) toxicity. The maternal toxicity was manifested as increased clinical signs, decreased body weight, body weight gain and food consumption. Fetal toxicity was manifested as decreased weight gain in pups. Since developmental effects occurred at the same exposure levels that caused maternal effects, maternal and fetal toxicity were comparable, and it was concluded that there is no increased susceptibility indicated by results from the 2-generation reproduction study. In rabbits, no developmental toxicity was seen up to the highest dose tested which demonstrated maternal toxicity, and therefore it is concluded that there is no evidence of increased susceptibility demonstrated in rabbits.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. There are no residual uncertainties in the toxicity database. Existing data are sufficient for endpoint selection for exposure/risk assessment. The fludioxonil toxicity database is complete with the exception of an immunotoxicity study, and acute and subchronic neurotoxicity studies. The immunotoxicity and acute and subchronic neurotoxicity studies are now required by new data requirements for conventional pesticide registration (40 CFR part 158). The available data do not show potential for neurotoxicity or immunotoxicity. The overall weight-of-evidence suggests that fludioxonil does not directly target the immune system. Further, there is no evidence of

neurotoxicity or neuropathology in the fludioxonil database. Therefore, the Agency does not believe that the immunotoxicity and acute and chronic neurotoxicity studies will result in a lower POD than that currently in use for overall risk assessment. Thus, the Agency believes that a database uncertainty factor is not needed to account for lack of these studies.

ii. There is no indication that fludioxonil is a neurotoxic chemical and therefore EPA finds no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that fludioxonil results in increased susceptibility of *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT, tolerance-level residues, and anticipated residues as follows: Anticipated residue values for apple, grapefruit, lemon, lime, orange, pear, tomato, head lettuce, leaf lettuce, grape, cherry, peach, and plum were generated from field trials; anticipated residues were also determined from processing studies for raisins, and for the juice of apple, grape, grapefruit, lemon, lime, orange and tomato. These data are reliable and will not underestimate the exposure and risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fludioxonil in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fludioxonil.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Based on the explanation in Unit IV.B.3, regarding residential use patterns, acute residential exposure to residues of fludioxonil is not expected. Therefore, since the acute aggregate risk assessment only includes exposure from food and water, no further calculations are necessary beyond the acute dietary analysis. There were no significant toxicological effects attributable to a single exposure (dose) for the general population or any other population subgroups; therefore these population subgroups were not included in this assessment. An acute dietary assessment was therefore conducted for the population subgroup females 13–49 years old. Using the exposure assumptions discussed in this unit for acute exposure, the acute aggregate exposure (food and water) to fludioxonil will occupy 15% of the aPAD for females 13–49 years old.

2. *Chronic risk.* Based on the explanation in IV.B.3, unit regarding residential use patterns, chronic residential exposure to residues of fludioxonil is not expected. Therefore, since the chronic aggregate risk assessment only includes exposure from food and water, no further calculations are necessary beyond the chronic dietary analysis. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic aggregate exposure to fludioxonil (food and water) utilized 88% of the cPAD for children 1–2 years old, the population subgroup receiving the greatest exposure. For the U.S. population the chronic aggregate exposure (food and water) utilized 26% of the cPAD.

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

Fludioxonil is currently registered for uses that could result in short- and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to fludioxonil. Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded that combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs for the most highly exposed subgroup, children 1–2 years old, of 250 for short-term exposures and 100 for intermediate-term exposures. Because EPA's level of concern for fludioxonil is a MOE of less than 100, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Fludioxonil is classified as a "Group D" chemical, as discussed previously, and not classifiable as to human carcinogenicity. However, EPA expects the cancer risk of fludioxonil to be negligible.

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

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (high-pressure liquid chromatography method AG–597B) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; *telephone number:* (410) 305–2905; *e-mail address: residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by section 408(b)(4) of FFDCA. The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, section 408(b)(4) of FFDCA requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for fludioxonil on pineapple.

VI. Conclusion

For the reasons described above, a time-limited tolerance is established for residues of fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile), in or on pineapple at 13 ppm. This tolerance expires on December 31, 2013.

VII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under sections 408(e) and 408(l)(6) of FFDCA. 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with sections 408(e) and 408(l)(6) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: January 24, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.516 is amended by alphabetically adding "pineapple" to the table in paragraph (b) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
Pineapple	13	12/31/13
* *	* *	* *

* * * * *

[FR Doc. 2011–2405 Filed 2–10–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0217; FRL–8858–3]

Clothianidin; Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of clothianidin in or on rice, seed. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). The tolerances expire on June 23, 2012.

DATES: This regulation is effective February 11, 2011. Objections and requests for hearings must be received on or before April 12, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see also* Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0217. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Marianne Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8043; e-mail address: *lewis.marianne@epa.gov.*

SUPPLEMENTARY INFORMATION: