Appendix 1—United States Environmental Protection Agency Human Studies Review Board

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List of Subjects in 40 CFR Part 180

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

Dated: July 11, 2008.

Debra Edwards,

Director, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0302; FRL–8369–5]

Fludioxonil; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fludioxonil in or on carambola (starfruit). 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 carambola. This regulation establishes a maximum permissible level for residues of fludioxonil in starfruit. The time-limited tolerance expires and is revoked on December 31, 2010.

DATES: This regulation is effective July 23, 2008. Objections and requests for hearings must be received on or before September 22, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0302. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. 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 either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (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. 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–2008–0302 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 September 22, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0302, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. 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 the fungicide fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile), in or on carambola at 10 parts per million (ppm). This time-limited tolerance expires and is revoked on December 31, 2010. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the CFR.

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 section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA and the new 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 Carambola and FFDCA Tolerances

The disease, Dothiorella fruit rot is a recent phenomenon in Florida and was documented as a major problem for citrus growers during the 2006–07 season. The current practice of dipping carambola in chlorine solution to remove other fungal pathogens has been ineffective in controlling Dothiorella fruit rot, and there are no other appropriate practices or materials available. The industry is also particularly vulnerable since it is still recovering from the 2005 hurricane season and the 2006–07 spring drought which delayed flowering and fruiting. A postharvest dip of fludioxonil has demonstrated effective management of Dothiorella fruit rot. Losses suffered were expected to be significant if fludioxonil were not available for post-harvest treatment as requested. After having reviewed the submission, EPA determined that emergency conditions exist for this State, and that the criteria for an emergency exemption are met. EPA has authorized under FIFRA section 18 the use of fludioxonil on carambola for control of Dothiorella fruit rot in Florida.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of fludioxonil in or on carambola. 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 and is revoked on December 31, 2010, 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 carambola 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 carambola 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 serve as the basis for persons in any State other than Florida to use this pesticide on this crop 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

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....''

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerance for residues of fludioxonil on carambola at 10 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance follows.

A. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 Starfruit'' at page 35 in docket ID number EPA–HQ–OPP–2008–0302.

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*. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, an acute dietary assessment assuming tolerance-level residues for all commodities with existing and proposed tolerances and default 100% crop treated (CT) information was conducted for the population subgroup females 13 to 49 years old. The estimated peak drinking water concentration of 132 parts per billion (ppb) was directly incorporated into the acute risk assessment. There were no appropriate 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. For food and drinking water, the exposure to females 13 to 49 yrs old (the most sensitive population subgroup) was 0.14 milligrams/kilogram/day (mg/kg/day), which utilized 14% 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 assumed tolerance-level residues for most commodities and 100% CT. Anticipated residue values for apple, grapefruit, lemon, lime, orange, and pear were generated from field trials. Anticipated residues were also determined from processing studies for apple, grapefruit, lemon, lime and orange juices. The mean drinking water estimate of 49 ppb was directly incorporated into the chronic assessment. For the U.S. population the exposure for food and water utilized 47% of the cPAD. The chronic dietary

risk estimate for the highest reported exposed population subgroup, children 1 to 2 years old, is 86% of the cPAD.

iii. *Cancer*. Fludioxonil is classified as a ''Group D'' chemical - not classifiable as to human carcinogenicity. Therefore a cancer dietary assessment was not performed.

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

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 exposure is estimated to be 132 ppb (peak concentration), and for chronic (non-cancer) exposures, 49 ppm (mean concentration), both levels for surface water concentrations. Ground water sources were not included in this assessment, as the EDWCs for this water source are minimal in comparison to surface water (0.11 ppb for both acute and chronic concentrations).

Modeled estimates of drinking water concentrations were entered directly into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 132 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 49 ppb was used to assess the contribution to drinking water.

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

Fludioxonil is currently registered for residential turf use, restricted to commercial applicators only. Since there are no short-term or intermediate-term dermal toxicity endpoints, only a toddler post-application assessment for incidental ingestion exposures to treated lawns was included (for all children/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 body weight (bw)/day, while the intermediate-term was determined to be 0.0074 mg/kg bw/day. The MOEs for combined non-dietary oral exposures were 770 for short-term exposures and 450 for intermediate-term exposures. These do not exceed the EPA's LOC for residential exposures (MOEs < 100).

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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

C. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA 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 pre-natal/post-natal exposure of rats. In rats, there was an increase in the number of fetuses and litters with dilated renal pelvis and dilated ureter. This finding was considered to be related to maternal toxicity rather than an indication of increased susceptibility. Therefore, it is concluded that there is no evidence of increased susceptibility in rats. In rats, developmental effects occurred in the presence of maternal effects. In rabbits, no developmental toxicity was seen up to the highest dose tested which demonstrated maternal toxicity. In the 2–generation rat reproduction study, offspring toxicity was seen at the dose that produced parental 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 maternal and fetal toxicity were comparable, it was concluded that there is no increased susceptibility in the 2–generation reproduction study.

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. The toxicity database for fludioxonil is complete.

ii. There is no indication that fludioxonil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fludioxonil results in increased susceptibility in *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. Anticipated residue values for apple, grapefruit, lemon, lime, orange, and pear were generated from field trials. Anticipated residues were also determined from processing studies for

apple, grapefruit, lemon, lime and orange juices. Data supporting the citrus crop group tolerance were used to estimate residues for carambola. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. Since the acute aggregate risk assessment includes exposure from food and water only, and the acute dietary analysis that was performed included both, no further calculations are necessary. An acute dietary assessment was conducted for the population subgroup females 13 to 49 years old. There were no appropriate toxicological effects attributable to a single exposure (dose) for the general population or other population subgroups; therefore only the subgroup of females 13 to 49 years old was included in this assessment. Using the exposure assumptions discussed in this unit for acute exposure, the acute aggregate exposure from food and water to fludioxonil will occupy 14% of the aPAD for Females 13 to 49 years old.

2. *Chronic risk*. Based on the explanation in the unit regarding residential use patterns, chronic residential exposure to residues of fludioxonil is not expected. Consequently, the chronic aggregate risk assessment includes exposure from food and water only. Because the chronic dietary analysis that was performed included both food and water, no further calculations are necessary for an aggregate chronic risk assessment. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fludioxonil from food and water will utilize 86% of the cPAD for children 1 to 2 years old the population group receiving the greatest exposure. For the U.S. population the exposure for food and water utilized 47% of the cPAD.

3. *Short-term and Intermediate-term risk*. Short-term 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 aggregated result in aggregate MOEs for the most highly exposed subgroup, Infants <1 year old, of 320 for short-term exposures and 130 for intermediate-term exposures. These do not exceed the level of concern for residential exposures (MOEs < 100).

4. *Aggregate cancer risk for U.S. population*. Fludioxonil is classified as a ''Group D'' chemical - not classifiable as to human carcinogenicity. Therefore a cancer aggregate assessment was not performed.

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

The methods used in previous field trial studies were similar to a method validated by the Analytical Chemistry Branch (ACB). Since adequate method validation and concurrent recoveries were attained in the field trial studies, EPA concludes that the ACB validated method is appropriate for enforcement.

Adequate enforcement methodology (high performance 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

There are no CODEX maximum residue levels for fludioxonil residues on carambola.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile), in or on starfruit at 10 ppm. This tolerance expires and is revoked on December 31, 2010.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances 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, *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 a FIFRA section 18 exemption under sections 408(e) and 408(l)(6) of FFDCA, such as the tolerances 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) (Public Law 104–4).

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

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: July 9, 2008.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

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

§ 180.516 Fludioxonil; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Starfruit	10	12/31/10

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[FR Doc. E8–16876 Filed 7–22–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 263

RIN 0970–AC15

Cost Allocation Methodology Applicable to the Temporary Assistance for Needy Families Program

AGENCY: Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule applies to the Temporary Assistance for Needy Families (TANF) program and requires States, the District of Columbia and the Territories (hereinafter referred to as the ''States'') to use the ''benefiting program'' cost allocation methodology in U.S. Office of Management and Budget (OMB) Circular A–87 (2 CFR part 225). It is the judgment and determination of HHS/ACF that the ''benefiting program'' cost allocation methodology is the appropriate methodology for the proper use of Federal TANF funds. The Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996 gave federally-recognized Tribes the opportunity to operate their own Tribal TANF programs. Federally-recognized Indian tribes operating approved Tribal TANF programs have always followed the ''benefiting program'' cost allocation methodology in accordance with OMB Circular A–87 (2 CFR part 225) and the applicable regulatory provisions at 45 CFR 286.45(c) and (d). This final rule contains no substantive changes to the proposed rule published on September 27, 2006.

EFFECTIVE DATE: This rule is effective July 23, 2008.

FOR FURTHER INFORMATION CONTACT: Robert Shelbourne, Director, State TANF Policy Division at (202) 401–5150, *rshelbourne@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: On September 27, 2006, ACF published a Notice of Proposed Rulemaking (NPRM) to add section 263.14 to 45 CFR part 263, requiring a State or Territory to use a benefiting program cost allocation methodology consistent with the general requirements of OMB Circular A–87 to allocate TANF costs. We provided a 60-day comment period that ended on November 27, 2006. We offered the public the opportunity to submit comments by surface mail, e-mail, or electronically via our Web site.

Comment Overview

After accounting for duplication, we received one comment on the NPRM. We have summarized the public comment and our response to it in Section II of the preamble to this final rule.

Table of Contents

I. Statutory Authority

We are issuing this regulation under the authority granted to the Secretary of Health and Human Services (HHS) by 42 U.S.C. 1302(a). Section 1302(a) authorizes the Secretary to make and publish such rules as may be necessary for the efficient administration of functions with which he is charged under the Social Security Act.

42 U.S.C. 617 limits the authority of the Federal government to regulate State conduct or enforce the TANF provisions of the Social Security Act, except as expressly provided. We interpret this