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[FR Doc. 2012–19987 Filed 8–14–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0657; FRL–9356–9]

S-Metolachlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of S-metolachlor in or on beet, garden, leaves, cilantro, leaves and coriander, seed. Interregional Research Project Number 4 requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 15, 2012. Objections and requests for hearings must be received on or before October 15, 2012, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0657, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; email address: *jackson.sidney@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 those engaged in the following activities:

- 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 to provide 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 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–2011–0657 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 October 15, 2012. 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–2011–0657, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 7, 2011 (76 FR 55329) (FRL–8886–7), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7898) by Interregional Research Project Number 4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.368 be amended by establishing tolerances for residues of the herbicide S-metolachlor, S-2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide, its R-enantiomer, and its metabolites, determined as the derivatives, 2-[2-ethyl-6-methylphenyl)amino]-1-propanol and 4-[2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, in or on cilantro, leaves, fresh at 8.0 parts per million (ppm) cilantro, leaves, dried at 8.0 ppm, coriander, seed at 0.13 ppm and beet, garden, leaves at 1.8 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.*

EPA received one comment to the Notice of Filing. That comment is addressed in Unit IV.C.

Based upon review of the data supporting the petition, EPA corrected the crop definition for ''cilantro'' to ''coriander'' and removed proposed tolerances for fresh and dried cilantro leaves. The reasons for these changes are explained in Unit IV.D.

III. 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 FFDCA section 408(b)(2)(D), and 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 for S-metolachlor including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with S-metolachlor follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

S-Metolachlor exhibits low acute toxicity via oral, inhalation, and dermal routes of exposure. It causes slight eye irritation, and is non-irritating dermally, but is a dermal sensitizer. In subchronic (metolachlor and S-metolachlor) and chronic (metolachlor) toxicity studies in dogs and rats decreased body weight and body weight gain were the most commonly observed effects. No systemic toxicity was observed when metolachlor was administered dermally. No neurotoxicity studies with metolachlor or S-metolachlor are available. However, there was no evidence of neurotoxic effects in the available toxicity studies. Prenatal developmental studies in the rat and rabbit with both metolachlor and S-metolachlor revealed no evidence of a qualitative or quantitative susceptibility in fetal animals. A 2-generation reproduction study with metolachlor in rats showed no evidence of parental or reproductive toxicity. There are no residual uncertainties with regard to pre- and/or postnatal toxicity. Metolachlor has been evaluated for carcinogenic effects in the mouse and the rat. Metolachlor did not cause an increase in tumors of any kind in mice. In rats, metolachlor caused an increase in benign liver tumors in rats but this increase was seen only at the highest dose tested and was statistically significant compared to controls only in females. There was no evidence of mutagenic or cytogenetic effects *in vivo* or *in vitro.* Based on this evidence, EPA has concluded that metolachlor does not have a common mechanism of carcinogenicity with acetochlor and alachlor which are structurally similar. Taking into account the qualitatively weak evidence on carcinogenic effects and the fact that the increase in benign tumors in female rats occurs at a dose 1,500 times the chronic reference dose (cRfD), EPA has concluded that the cRfD is protective of any potential cancer effect.

Specific information on the studies received and the nature of the adverse effects caused by S-metolachlor as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document entitled, ''S-Metolachlor. Human Health Risk Assessment for the Section 3 Requests for Use on Coriander (Cilantro) and Garden Beet Leaves,'' p. 13 in docket ID number EPA–HQ–OPP–2011–0657.

B. 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 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 dose at which no adverse effects are observed (the NOAEL) and the lowest dose 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 S-metolachlor used for human risk assessment is discussed in Unit III. of the final rule published in the **Federal Register** of September 17, 2010 (75 FR 56899) (FRL–8842–3).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to S-metolachlor, EPA considered exposure under the petitioned-for tolerances as well as all existing metolachlor and S-metolachlor tolerances in 40 CFR 180.368. EPA assessed dietary exposures from S-metolachlor in food as follows:

Both the acute and chronic analyses assume tolerance-level residues on all crops with established, pending, or proposed tolerances for metolachlor and/or S-metolachlor. In cases where separate tolerance listings occur for both metolachlor and S-metolachlor on the same commodity, the higher value of the two is used in the analyses.

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for S-metolachlor. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), 1994–1996 and 1998. As to residue levels in food, EPA assumed tolerance level residues for all uses, 100 percent crop treated (PCT) for all commodities and default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's Nationwide CSFII, 1994–1996 and 1998. As to residue levels in food, EPA assumed tolerance level residues for all uses, 100 PCT for all commodities and default processing factors.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-

use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determine a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to S-metolachlor. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for S-metolachlor. Tolerance level residues and 100 PCT were assumed for all food commodities with existing tolerances, and default processing factors.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for S-metolachlor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of S-metolachlor. 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), Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) Screening Concentration in Ground Water (SCI–GROW) models and the USGA National Water-Quality Assessment (NAWQA) Program monitoring data, the Agency calculated conservative estimated drinking water concentrations (EDWCs) of S-metolachlor and metolachlor originating from ground water and surface water. EDWCs for metolachlor and metolachlor were calculated for both the parent compound and the ethanesulfonic acid (ESA) and oxanilic acid (OA) degradates. The environmental fate data have been bridged from the racemic mixture (50:50) of metolachlor to the newer isomer (88:12) S-metolachlor, based on similarities in environmental fate behavior. Tier I and Tier II screening models were employed for this assessment. For surface water, PRZM/EXAMS and FIRST Version1.1.1 models were used to estimate drinking water concentrations for the parent S-metolachlor and the ESA and OA degradates, respectively. The SCI–GROW model was used to predict the maximum acute and chronic concentrations present in shallow groundwater. Current NAWQA monitoring data were also used to determine EDWCs. Based on monitoring and modeling data, total EDWCs for peak and average surface water respectively are 219 ppb (78 ppb parent + 48 ppb metolachlor ESA+ 94 ppb metolachlor OA) and 119 ppb (18 ppb parent + 34 ppb metolachlor ESA+ 67 ppb metolachlor OA). Groundwater EDWCs (peak and average) are 126 ppb (33 ppb parent + 64 ppb metolachlor ESA+ 30 ppb metolachlor OA).y67

For acute exposures are estimated to be 219 ppb for surface water and 126 ppb for ground water.

For chronic exposures for non-cancer assessments are estimated to be 110 ppb for surface water and 126 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 219 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment (cancer and non-cancer), the water concentration of value 126 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).

S-Metolachlor is currently registered for the following uses that could result in residential exposures: Residential lawns or turf by professional applicators. Pennant MAGNUM\TM (EPA Reg. No. 100–950) is labeled for use on commercial (sod farm) and residential warm-season turf grasses and other non-crop land including golf courses, sports fields, and ornamental gardens. Since Pennant MAGNUM\TM is not registered for homeowner purchase or use (i.e., used by professional/commercial applicators), the only potential short-term residential risk scenario anticipated is post-application hand-to-mouth exposure of children playing on treated lawns. S-metolachlor incidental oral exposure is assumed to include hand-to-mouth exposure, object-to-mouth exposure and exposure through incidental ingestion of soil. Small children are the population group of concern. Although the type of site that S-metolachlor may be used on varies from golf courses to ornamental gardens, the scenario chosen for risk assessment (residential turf use) represents what the Agency considers the likely upper-end of possible 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.''

Other than metolachlor, EPA has not found S-metolachlor to share a common mechanism of toxicity with any other substances, and S-metolachlor does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that S-metolachlor 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.*

D. 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 safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No increase in susceptibility was seen in developmental toxicity studies in rat and rabbit or reproductive toxicity studies in the rat. Toxicity to offspring was observed at dose levels the same or greater than those causing maternal or

parental toxicity. Based on the results of developmental and reproductive toxicity studies, there is not a concern for increased qualitative and/or quantitative susceptibility following *in utero* exposure to metolachlor or S-metolachlor.

3. *Conclusion.* EPA has determined that reliable data show 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 S-metolachlor is complete, except for an immunotoxicity and acute and subchronic neurotoxicity studies required under the amendments to the data requirements. However, based on the results of the available toxicity studies, there is no evidence of immunotoxicity or neurotoxicity. Thus, EPA does not expect these data to change the existing POD for risk assessment.

ii. There is no indication that S-metolachlor 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 S-metolachlor causes an 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. The dietary food exposure assessments were performed based on 100 PCT, tolerance-level residues for all uses, and default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to S-metolachlor in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by S-metolachlor.

E. 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to S-metolachlor will occupy 1.5% of the aPAD for all infants < 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to S-metolachlor from food and water will utilize 11.6% of the cPAD for all infants < 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of S-metolachlor is not expected.

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

S-metolachlor is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to S-metolachlor. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures including incidental oral exposure from all possible sources: Combined hand-to-mouth, object-to-mouth, and soil ingestion oral exposure result in an aggregate MOE of 860. Because EPA's level of concern for S-metolachlor is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, S-metolachlor is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the PODs used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for S-metolachlor.

5. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A. of this document, EPA has concluded that the chronic RfD is protective of cancer effects, and, as shown above, the chronic risk assessment indicated that aggregate exposure to S-metolachlor does not pose a risk of concern.

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, or to infants and children from aggregate exposure to S-metolachlor residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies (gas chromatography with nitrogen phosphorous detector (GC/NPD) method (Method I) for determining residues in/on crop commodities and a gas chromatography with mass spectroscopy detector (GC/MSD) method (Method II) for determining residues in livestock commodities) are available to enforce the tolerance expression. IR–4 and Syngenta have proposed a high pressure liquid chromatography with mass spectroscopy/mass spectroscopy (HPLC/MS/MS) enantiomer-specific method for the enforcement of the proposed tolerances, Method 1848–01. The method uses a chiral HPLC column to separate out the S-enantiomers (SYN506357 and SYN508500) of the hydrolysis products CGA–37913 and CGA–49751. This method has been determined to be adequate for enforcement purposes.

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; email 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 FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations 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, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Neither Codex, Canada, or Mexico has established or proposed maximum residue limits (MRLs) for S-metolachlor on cilantro or garden beet leaves.

C. Response to Comments

In the one comment received, the commenter objected to EPA approving use of this chemical and asked that EPA ban further use of this ''toxic chemical.'' The commenter went on to state that there are several toxic effects attributed to this chemical including evidence of carcinogenicity. The Agency understands the commenter's concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances have demonstrated that the pesticide meets the safety standard imposed by that statute. When new or amended tolerances are requested for residues of a pesticide in food or feed, the Agency, as is required by section 408 of the FFDCA, estimates the risk of the potential exposure to these residues. The Agency has concluded after this assessment, which includes the consideration of long-term animal studies with metolachlor and S-metolachlor, that there is a reasonable certainty that no harm will result from aggregate (food, water and non-dietary) human exposure to S-metolachlor and that, accordingly, the tolerances that will be established by this rule are ''safe.'' That assessment included a consideration of S-metolachlor's carcinogenic potential. As discussed in Unit III.A., EPA concluded that any potential cancer risk from S-metolachlor is addressed by the chronic risk assessment. That risk assessment showed no risks of concern.

D. Revisions to Petitioned-For Tolerances

The Agency does not differentiate between dry and fresh cilantro leaves. Therefore, the Agency is modifying the tolerance proposal and establishing a tolerance for S-metolachlor residues on cilantro, leaves.

V. Conclusion

Therefore, tolerances are established for residues of S-metolachlor in or on beet, garden, leaves at 1.8 ppm, cilantro, leaves at 8.0 ppm, and coriander, seed at 0.13 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this 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 on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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 FFDCA section 408(n)(4). 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).

VII. 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: August 8, 2012.

Daniel J. Rosenblatt,

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 180.368 is amended by alphabetically adding the following commodities to the table in paragraph (a)(2) to read as follows:

§ 180.368 S-metolachlor; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * * * *	
Beet, garden, leaves	1.8

Commodity	Parts per million
* * * * *	
Cilantro, leaves	8.0
Coriander, seed	0.13
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0395; FRL–9357–5]

Fludioxonil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil in or on multiple commodities which are identified and discussed later in this document, associated with pesticide petition (PP) 1E7853 and PP 1E7870. This regulation additionally revises several established tolerances, and removes several established permanent and time-limited tolerances. Interregional Research Project Number 4 (IR–4) and Syngenta Crop Protection, LLC, requested the tolerances associated with PP 1E7853 and PP 1E7870, respectively, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 15, 2012. Objections and requests for hearings must be received on or before October 15, 2012, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0395, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; email address: *nollen.laura@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 those engaged in the following activities:

- 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 to provide 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 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–2011–0395 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 October 15, 2012. 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–2011–0395, by one of the following methods:

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2011–0395 by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL–8880–1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition, PP 1E7853, by IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.516 be amended by establishing tolerances for residues of the fungicide fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1-*H*-pyrrole-3-carbonitrile), in or on acerola at 5.0 parts per million (ppm); atemoya at 20 ppm; biriba at 20 ppm; cherimoya at 20 ppm; custard apple at 20 ppm; feijoa at 5.0 ppm; guava at 5.0 ppm; ilama at 20 ppm; jaboticaba at 5.0 ppm; passionfruit at 5.0 ppm; soursop at 20 ppm; starfruit at 5.0 ppm; sugar apple at