Commodity	Parts per million
Cherry	0.40
Cucumber	0.20
Grape	0.70
Squash	0.05
Strawberry	0.50

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

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

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

■ 3. Add § 180.1354 to subpart D to read as follows:

§ 180.1354 Flutianil; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for indirect and inadvertent residues of the fungicide flutianil, including its metabolites and degradates, in or on all food commodities not listed in § 180.697(a), when residues are present therein as a result of uptake by crops rotated into fields containing the crops in § 180.697(a) that were previously treated with flutianil.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0211; FRL–9973–11]

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 sugarcane, cane and sugarcane molasses. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 21, 2018. Objections and requests for hearings must be received on or before May 21, 2018, 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–2017–0211, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., 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: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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://www.ecfr.gov/cgi-bin/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–2017–0211 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 May 21, 2018. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0211, 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 CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (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.html.*

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 15, 2017 (82 FR 43352) (FRL–9965–43), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F8519) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide S-metolachlor in or on sugarcane at 0.4 parts per million (ppm) and sugarcane molasses at 1.5 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is

establishing a tolerance for sugarcane, cane below the level requested. The reason for this change is 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 its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The existing toxicological database is primarily comprised of studies conducted with metolachlor. However, bridging studies indicate that the metolachlor toxicology database can be used to assess toxicity for S-metolachlor. 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 in rabbits when metolachlor was administered dermally. There was no evidence of neurotoxic effects in the available toxicity studies, and there is no evidence of immunotoxicity in the submitted mouse immunotoxicity study.

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. Although treatment with metolachlor did not result in an increase in treatment-related tumors in male rats or in male or female mice, metolachlor caused an increase in liver tumors in female rats. There was no evidence of mutagenic or cytogenetic effects *in vivo* or *in vitro.* Based on the information available in 1994, metolachlor was classified as a Group C possible human carcinogen, in accordance with the 1986 Guidelines for Carcinogen Risk Assessment. Based on that classification and consistent with the data available at that time, EPA determined that a non-linear approach (*i.e.,* reference dose (RfD)) would be protective for all chronic toxicity, including carcinogenicity, that could result from exposure to metolachlor.

In 2017, EPA re-assessed the cancer classification for metolachlor in order to take into account additional mechanistic studies on s-metolachlor that were submitted to assess a human relevance framework analysis for a mitogenic mode of action (MOA) for liver tumors in female rats. Based on comparable effects of S-metolachlor and metolachlor shown in several associative events supporting the mode of action hypothesis, the Agency concluded that the *in vitro* and *in vivo* data reasonably explains the tumorigenic effects of metolachlor and adequately demonstrates dose and temporal concordance to support key events for the MOA leading to liver tumors in female rats. Specifically, the Agency found that the development of liver tumors in rats orally administered metolachlor is initiated by activation of constitutive androstane receptor (CAR) in liver hepatocytes followed by altered gene expression, transient increased cell proliferation, increased hepatocellular foci, and hepatocyte toxicity (increased liver weight and liver hypertrophy).

Consequently, in accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March 2005), EPA has reclassified metolachlor/S-metolachlor as ''Not Likely to be Carcinogenic to Humans'' at doses that do not induce cellular proliferation in the liver. This classification was based on convincing evidence of a CAR-mediated mitogenic MOA for liver tumors in female rats. Because the current chronic RfD is protective for any proliferative responses in the liver and the other key events in the MOA for the formation of liver tumors, a non-linear approach (*i.e.,* RfD) would adequately account for all the chronic toxicity, including carcinogenicity, that could result from exposure to metolachlor/S-metolachlor.

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 the document titled ''*S-metolachlor—Human Health Risk Assessment for the Establishment of Permanent Tolerances for Use of the Herbicide on Sugarcane (PP#6F8519)*'' on pages 36–42 in docket ID number EPA–HQ–OPP–2017–0211.

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://www2.epa.gov/pesticide-science-and-*

assessing-pesticide-risks/assessing-human-health-risk-pesticides.

A summary of the toxicological endpoints for S-metolachlor used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR S-METOLACHLOR FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 300 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 3.0 mg/kg/day. aPAD = 3.0 mg/kg/day	Developmental Toxicity Study—Rat. Metolachlor LOAEL = 1,000 mg/kg/day based increased incidence of death, clinical signs (clonic and/or tonic convulsions, excessive salivation, urine-stained abdominal fur and/or excessive lacrimation) and decreased body weight gain.
Chronic dietary (All populations)	NOAEL = 9.7 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.097 mg/kg/day. cPAD = 0.097 mg/kg/day	One Year Chronic Toxicity—Dog. Metolachlor LOAEL = 33 mg/kg/day based decreased body weight gain in females.
Incidental oral short-term (1 to 30 days).	NOAEL = 50 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity Study—Rat. S-metolachlor LOAEL = 500 mg/kg/day based on increased incidence of clinical signs, decreased body weight/body weight gain, food consumption and food efficiency seen in maternal animals.
Cancer (Oral, dermal, inhalation).	Classification: Metolachlor/S-metolachlor has been classified as ''Not Likely to be Carcinogenic to Humans'' at doses that do not induce cellular proliferation in the liver, with risk quantitated using a non-linear (RfD) approach.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = Lowest-observed-adverse-effect-level. LOC = Level of concern. mg/kg/day = Milligram/kilogram/day. MOE = Margin of exposure. NOAEL = No-observed-adverse-effect-level. PAD = Population adjusted dose (a = Acute, c = Chronic). RfD = Reference dose. UF = Uncertainty factor. UF_A = Extrapolation from animal to human (interspecies). UF_H = Potential variation in sensitivity among members of the human population (intraspecies).

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 S-metolachlor and metolachlor tolerances in 40 CFR 180.368. EPA assessed dietary exposures from S-metolachlor and metolachlor in food as follows:

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) National Health and Nutrition Examination Survey/What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance-level residues and 100 PCT.

iii. *Cancer.* 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. Therefore, a separate quantitative cancer exposure assessment is unnecessary since the chronic dietary risk estimate will be protective of potential cancer risk.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for S-metolachlor. Tolerance-level residues and 100 PCT were assumed for all food commodities.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

The Agency assessed parent metolachlor, and the metabolites CGA–51202 (metolachlor-OA), CGA–40172, and CGA–50720 together in the drinking water assessment using a total toxic residues (TTR) approach where half-lives were recalculated to collectively account for the parent and the combined residues of concern.

Based on the Surface Water Concentration Calculator (SWCC), the Pesticide Root Zone Model Ground Water (PRZM GW), and the Screening Concentration in Ground Water (SCI–GROW), the estimated drinking water concentrations (EDWCs) of S-metolachlor and its metabolites for acute exposures are estimated to be 371 parts per billion (ppb) for surface water and 1,060 ppb for ground water, and for chronic exposures are estimated to be 43.70 ppb for surface water and 978 ppb in 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 1,060 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 978 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: On commercial (sod farm) and residential warm-season turf grasses and other non-crop land including golf courses, sports fields, and ornamental gardens. EPA assessed residential exposure using the following assumptions: For residential handlers, in previous human health risk assessments for S-metolachlor inhalation exposure/risk to residential handlers was assessed and resulted in no risks of concern. However, all registered S-metolachlor labels with residential use sites require that handlers wear specific clothing (*e.g.,* long-sleeve shirt/long pants) and personal protective equipment (*e.g.,* gloves). Based on current policy, the Agency assumes these products are not intended for homeowner use and, therefore, a quantitative residential handler assessment was not conducted.

For residential post-application, there is the potential for short-term incidental oral exposure for individuals exposed as a result of being in an environment that has been previously treated with S-metolachlor. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenario: Hand-to-mouth incidental oral exposure of children 1–2 years old playing on turf treated with S-metolachlor.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*.

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 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 website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

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.* There was no evidence of increased quantitative or qualitative fetal susceptibility in the prenatal developmental studies in rats and rabbits or in the reproductive toxicity study in rats, with either metolachlor or S-metolachlor. In general, significant developmental toxicity was not seen in rats or rabbits with either compound. The only effects observed in fetal animals were in the rat prenatal developmental study and included slightly decreased number of implantations per dam, decreased number of live fetuses/dam, increased number of resorptions/dam and significant decrease in mean fetal body weight. These effects occurred at maternally toxic doses (1,000 mg/kg/day).

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 for all scenarios assessed as part of EPA's determination of safety for S-metolachlor. This decision is based on the following findings:

i. The toxicology database for metolachlor and S-metolachlor is complete, with the exception of a required subchronic inhalation study for metolachlor. Although the Agency has determined that a 10X database uncertainty factor should be retained to account for the lack of the subchronic inhalation study, the Agency does not expect inhalation exposures to result from the use of S-metolachlor.

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 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. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. 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 incidental oral exposure of children 1 to less-than 2 years old. 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 acute PAD (aPAD) and chronic PAD (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 6.1% of the aPAD for all infants less than 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 58% of the cPAD for all infants less than 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 result in an aggregate MOE of 700 for children 1–2 years old, the only population group of concern. Because EPA's level of concern for S-metolachlor is a MOE of 100 or below, this MOE is 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 POD 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 discussed in Unit III.A, the chronic dietary risk assessment is protective of any potential cancer effects. Based on the results of that assessment, EPA concludes that S-metolachlor is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methodology is available for enforcing the established and recommended tolerances. PAM Vol. II, Pesticide Regulation Section 180.368, lists a gas chromatography with nitrogen-phosphorus detector (GC/NPD) method (Method I) for determining residues in/on plant commodities and a gas chromatography with mass selective detector (GC/MSD) method (Method II) for determining residues in livestock commodities. These methods determine residues of metolachlor and its metabolites as either CGA–37913 or CGA–49751 following acid hydrolysis.

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.

The Codex has not established any MRLs for either S-metolachlor or metolachlor.

C. Response to Comments

One comment was received in response to the notice of filing. The commenter was against the establishment of any tolerances for S-metolachlor and stated in part ''allow zero tolerance. Allow zero residue'' and ''no animals or people should be eating any toxic chemicals.''

Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these S-metolachlor tolerances are safe. The commenter has provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerances

Although the petitioner requested a tolerance on sugarcane at 0.4 ppm, EPA is establishing the tolerance at 0.20 ppm based on available field trial data and the use of average values in the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedure instead of every individual sample that the petitioner used. The Agency is also establishing the tolerance for ''sugarcane, cane'' to be consistent with its food and feed commodity vocabulary.

V. Conclusion

Therefore, tolerances are established for residues of S-metolachlor in or on sugarcane, cane at 0.20 ppm and sugarcane molasses at 1.5 ppm.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: February 28, 2018.

Michael L. Goodis,

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 § 180.368, add alphabetically entries for ''Sugarcane, cane'' and ''Sugarcane, molasses'' to the table in paragraph (a)(2) to read as follows:

§ 180.368 Metolachlor; tolerances for residues.

* * * * *

(a)(2) * * *

Commodity	Parts per million
* * * * *	
Sugarcane, cane	0.20
Sugarcane, molasses	1.5
* * * * *	

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[FR Doc. 2018–05641 Filed 3–20–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 13–249; FCC 17–119]

Revitalization of the AM Radio Service

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, information collection requirements adopted in the Commission's Third Report and Order, FCC 17–119. This document is consistent with the Third Report and Order, which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of the rules.

DATES: The rule amendments to 47 CFR 73.151(c)(1)(ix) and (x) and (c)(3), 47 CFR 73.154(a), and 47 CFR 73.155, published at 82 FR 51161, November 3, 2017, are effective on March 21, 2018.

FOR FURTHER INFORMATION CONTACT: Cathy Williams by email at *Cathy.Williams@fcc.gov* and telephone at (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that, on March 8, 2018, OMB approved information collection requirements contained in the Commission's Report and Order, FCC 17–119, published at 82 FR 51161. The OMB Control Number is 3060–0991. The Commission publishes this notice as an announcement of the effective date of those information collection requirements.

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on March 8, 2018, for the information collection requirements contained in 47 CFR 73.151(c)(1)(ix) and (x) and (c)(3), 47 CFR 73.154(a), and 47 CFR 73.155, as amended, in the Commission's Report and Order, FCC 17–119. Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–0991. The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0991.

OMB Approval Date: March 8, 2018.

OMB Expiration Date: March 31, 2021.

Title: AM Measurement Data.

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 1,800 respondents; 3,135 responses.

Estimated Time per Response: 0.50 hours–25 hours.

Frequency of Response: Recordkeeping requirement, Third Party disclosure requirement, On occasion reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 151, 152, 154(i), 303, and 307 of the Communications Act of 1934, as amended.

Total Annual Burden: 20,200 hours.

Total Annual Cost: $1,131,500.

Nature and Extent of Confidentiality: There is no need for confidentiality treatment with this collection of information.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: The Commission revised this information collection to reflect the September 22, 2017, adoption of the Third Report and Order in MB Docket No. 13–249, FCC 17–119, *In the Matter of Revitalization of AM Radio*