PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In subpart D, add § 180.1380 to read as follows:

§ 180.1380 Pseudomonas fluorescens strain ACK55; exemption from the requirement of a tolerance.

Residues of Pseudomonas fluorescens strain ACK55 are exempt from the requirement of a tolerance in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2021–22105 Filed 10–8–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

EPA–HQ–OPP–2020–0511; FRL–8667–01–OCSPP]

Clothianidin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide clothianidin in or on food and feed commodities (other than those covered by a higher tolerance) in food/feed handling establishments. McLaughlin Gormley King Company D/B/A MGK requested tolerances for these commodities under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 12, 2021. Objections and requests for hearings must be received on or before December 13, 2021 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–2020–0511, 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. 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.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; 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 Publishing 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(g), 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–2020–0511 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 December 13, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although at this time, EPA strongly encourages those interested in submitting objections or a hearing request, to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), *https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf*. At this time, because of the COVID–19 pandemic, the judges and staff of the Office of Administrative Law Judges are working remotely and not able to accept filings or correspondence by courier, personal deliver, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a person should utilize the OALJ e-filing system, at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf*.

Although EPA's regulations require submission via U.S. Mail or hand deliver, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is impossible for a person to submit documents electronically or receive service electronically, *e.g.,* the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564–6281. If a person is without access to a computer and must file documents by U.S. Mail, the person shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

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–

2020–0511, 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.
- *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 October 27, 2020 (85 FR 68030) (FRL–10015–86), 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 0F8869) by McLaughlin Gormley King Company D/B/A MGK, 7325 Aspen Lane N, Minneapolis, MN 55428. The petition requested that 40 CFR 180.586(a)(1) be amended by establishing tolerances for residues of the insecticide clothianidin, (*E*)-*N*-[(2-Chloro-5-thiazolyl)methyl]-*N*′-methyl-*N*″-nitroguanidine, in or on all food items in food handling establishments where food and food products are held, processed, prepared, and/or served at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by McLaughlin Gormley King Company D/B/A MGK, the registrant, which is available in the docket, *http://www.regulations.gov*. There was one, non-substantive comment received on November 8, 2020, in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing tolerances that vary from what the petitioners sought. The reasons for these changes are explained in detail in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the 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 the 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 the 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 therein, 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 clothianidin in or on food and feed commodities (other than those covered by a higher tolerance).

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings and republishing the same sections is unnecessary; EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has recently published a tolerance rulemaking for clothianidin, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to clothianidin and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological Profile. For a discussion of the Toxicological Profile of clothianidin, see Unit III.A. of the November 25, 2019 rulemaking (84 FR 64772) (FRL–10000–64).

Toxicological Points of Departure/Levels of Concern. A summary of the toxicological effects of clothianidin, including the specific information on the studies received, the nature of the adverse effects caused by clothianidin, the no observed adverse effects 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 entitled ''Clothianidin: Draft Human Health Risk Assessment in Support of Registration Review,'' dated September 7, 2017. This document can be found in docket ID number EPA–HQ–OPP–2011–0865.

Exposure Assessment. EPA has updated the exposure assessments of clothianidin to include the petitioned-for tolerances in addition to exposures associated with existing tolerances for clothianidin in 40 CFR 180.586. The acute and chronic dietary exposure assessments for clothianidin were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM–FCID™, Version 3.16, which incorporates consumption data from USDA's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008.

The acute dietary exposure assessment is based on tolerance-level residues for all commodities since EPA typically does not include FHE uses in acute dietary assessments. In addition, the acute dietary exposure assessment assumes 100% crop treated (PCT) and incorporates the modeled EDWCs. Therefore, the resulting exposure and risk estimates are conservative.

The partially refined chronic dietary exposure assessment is based on average field trial residues and assumes 100 PCT. Average residues from representative commodities were extrapolated to similar commodities. Because thiamethoxam, which also breaks down into clothianidin residues, is also registered for FHE use, EPA accounts for clothianidin residues from both thiamethoxam and clothianidin FHE uses in the chronic assessment. For these analyses, a residue input value for FHE use was entered for all other commodities in DEEM–FCID™ not registered for direct use. Default processing factors were used, except where empirical factors derived from processing studies were available.

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.

EPA also used the same estimates for potential drinking water exposures as reflected in the November 25, 2019, rulemaking. Since the proposed use is for indoor applications, a new drinking water assessment was not needed.

Clothianidin is registered for uses that may result in residential (non-occupational) exposures. EPA has assessed the potential for short-term post-application exposure; other exposures are not expected. No residential risks of concern were identified. For aggregate risk assessment, EPA used the risk estimates from the combined dermal and inhalation exposures for adults from indoor aerosol can usage and from the combined dermal, inhalation, and incidental oral exposures for children 1 to less than 2 years old from treated indoor surfaces.

Safety Factor for Infants and Children. Section 408(b)(2)(C) of the 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 10 times, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA determined reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x because: (1) The toxicology data base is complete and includes developmental neurotoxicity (DNT), adult immunotoxicity and developmental immunotoxicity studies; (2) EPA characterized the degree of concern for the quantitative susceptibility observed in the clothianidin 2-generation reproduction and DNT studies as low based on the clear NOAELs for the offspring effects and the selection of regulatory doses that are protective of those effects; (3) the rat is the most sensitive species tested, and the NOAEL and LOAEL selected from the two-generation reproduction study in rats are protective of effects observed in the toxicology database, including the DNT and developmental immunotoxicity studies; (4) there are no residual uncertainties for pre- and/or post-natal toxicity; (5) EPA is regulating the use of clothianidin based upon the most sensitive offspring effects observed in the reproduction toxicity study, and therefore the risk assessment is protective of these and other effects that occurred at higher doses; (6) the exposure databases (*e.g.,* dietary food, drinking water, and residential) are complete; and (7) the risk assessment for each potential exposure scenario does not underestimate potential exposure and risk for infants or children.

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 population adjusted dose (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

The acute dietary risk estimates for clothianidin are 9.5% of the aPAD for the U.S. general population, and 29% of the aPAD for children 1 to 2 years old (the most highly exposed population subgroup). The chronic dietary risk estimates are 3.9% of the cPAD for the U.S. general population, and 9.4% of the cPAD for infants less than 1-year old (the most highly exposed population subgroup). Because both are below the 100% of the relevant PAD, these risk estimates are not of concern.

The short-term aggregate risk assessments resulted in MOEs of 150 to 490. For clothianidin, the LOC for short-term risk is an MOE of 100. As the resulting aggregate MOEs exceed the LOC of 100, short-term aggregate risk estimates are not of concern. Intermediate-term and long-term residential exposures are not expected.

Clothianidin is classified as ''Not Likely to be Carcinogenic to Humans;'' therefore, cancer risk is not a concern and cancer risks are not quantified.

Based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the U.S. general population, or to infants and children, from aggregate exposure to clothianidin residues. More detailed information on the subject action to establish a tolerance in or on food and feed commodities (other than those covered by a higher tolerance) can be found at *http://www.regulations.gov* in the document entitled ''Clothianidin. Petition for the Establishment of Permanent Tolerances and Registration for Use in Food Handling Establishment,'' dated July 15, 2021. This document can be found in docket ID number EPA–HQ–OPP–2020–0511.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate Liquid Chromatograph/Mass Spectrometer/Mass Spectrometer (LC/MS/MS) methods are available for enforcing tolerances of clothianidin residues in/on crop (Morse Method #Meth-164—modified, RM–39C–1, or Bayer Method 00552) and livestock (Bayer Method 00624) matrices.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, 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). Codex 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. Although EPA may establish a tolerance that is different from a Codex MRL, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has not established MRLs for food commodities based on the petitioned-for use in food handling establishments.

C. Revisions to Petitioned-For Tolerances

The petition described the use of clothianidin in or on ''all food items in food handling establishments where food and food products are held, processed, prepared and/or served.''

EPA has revised this language for the requested tolerance to read ''Food and feed commodities (other than those covered by a higher tolerance) in food/feed handling establishments.''

V. Conclusion

Tolerances are established for residues of the insecticide clothianidin in or on food and feed commodities (other than those covered by a higher tolerance) at 0.01 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). 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: October 5, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In § 180.586, amend paragraph (a)(1) by

■ a. Designating the table as table 1; and

■ b. In newly redesignated table 1, adding in alphabetical order an entry for ''Food and feed commodities (other than those covered by a higher tolerance) in food/feed handling establishments''.

The additions read as follows:

§ 180.586 Clothianidin; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * * * *	
Food and feed commodities (other than those covered by a higher tolerance) in food/feed handling establishments	0.01
* * * * * * *	

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[FR Doc. 2021–22104 Filed 10–8–21; 8:45 am]

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