bis(hydroxymethyl)-, 1,3-dicyclohexyl ester (PMN P–18–337; CAS No. 2222732–46–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=95.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[FR Doc. 2021–24789 Filed 11–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0512; FRL–8668–01–OCSPP]

Pyriproxyfen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyriproxyfen, including its metabolites and degradates, in or on egg; poultry, fat; poultry, meat; and poultry, meat byproducts. 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 November 15, 2021. Objections and requests for hearings must be received on or before January 14, 2022 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–2020–0512, 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.

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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–2020–0512 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 January 14, 2022. 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–2020–0512, 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 0F8870) by McLaughlin Gormley King Company D/B/A MGK, 7325 Aspen Lane N, Minneapolis, MN 55428. The petition requested that 40 CFR 180.510 be amended by establishing tolerances for residues of the insecticide pyriproxyfen in or on eggs and all tissues (except poultry fat) at 0.03 parts per million (ppm) and poultry fat at 0.04 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 for this action, docket ID EPA–HQ–OPP–2020–0512, at *http://www.regulations.gov.* No substantive public comments were received 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 pyriproxyfen in or on egg; poultry, fat; poultry, meat; and poultry, meat byproducts. 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 previously published several tolerance rulemakings for pyriproxyfen, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to pyriproxyfen 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 pyriproxyfen, see Unit III.A. of the February 22, 2016 rulemaking (81 FR 8658) (FRL–9941–68).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, please refer to the September 25, 2017 risk assessment supporting the *Registration Review* for pyriproxyfen entitled, ''Pyriproxyfen: Human Health Draft Risk Assessment for Registration Review'' by going to *http://www.regulations.gov.* The referenced document is available in docket ID number EPA–HQ–OPP–2011–0677.

Exposure assessment. Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerances. These updates are discussed in this section; for a detailed description of the rest of the EPA approach to and assumptions for the exposure assessment, please refer to the 2017 draft human health risk assessment for *Registration Review.*

Since the recommended tolerance levels (0.1 ppm) are equal to, and not aggregated with, the existing food handling establishment (FHE) tolerance levels (0.1 ppm) for all food commodities established as part of a 2001 rulemaking (66 FR 14852) (FRL–6766–6) included in the dietary (food + drinking water) exposure and risk assessment supporting this rule, no updates to the dietary assessment are required. An unrefined chronic dietary (food + drinking water) exposure assessment was conducted using tolerance-level residues recommended under the 2017 pyriproxyfen draft human health risk assessment for *Registration Review.* This 2017 assessment assumed 100% crop treated and EPA's 2018 default processing factors. Drinking water was incorporated directly into the chronic dietary assessment. The chronic dietary (food + drinking water) exposures were estimated at 5.8% of the cPAD for the U.S. general population and 15% of the cPAD for the most highly exposed population subgroup (children 1 to 2 years old) and are below EPA's level of concern (LOC), less than 100% of the cPAD (<100% cPAD).

Since no short- or intermediate-term dermal and inhalation points of departure (PODs) were selected for pyriproxyfen and there are no long-term inhalation exposure scenarios for the registered uses of pyriproxyfen, the only exposure scenarios are for post-application incidental oral exposures for children 1 to less than 2 years old (1 to <2 years old) for all durations of exposure and long-term dermal exposures for children 1 to <2 years old and adults. Residential post-application short-, intermediate-, and long-term incidental oral risk estimates from contact with treated lawns, treated indoor areas and contact with pets treated with shampoo and spot-on applications to pets for children 1 to <2 years old result in no risks of concern (*i.e.,* all margins of exposure (MOEs) are greater than the LOC (> LOC of 100); MOEs range from 4,700 to 9,000,000.

With use of chemical-specific dust torsion exposure data for pyriproxyfen pet collars, long-term combined (dermal + incidental oral) risk estimates for children 1 to <2 years old also result in no risks of concern (*i.e.,* all combined MOEs are >100); MOEs range from 570 to 2,300. Further, long-term adult dermal risks are not of concern; MOEs range from 1,600 to 6,400.

Cumulative exposures. 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's assessment of cumulative exposures has not changed since the February 22, 2016 rulemaking (81 FR 8658) (FRL–9941–68). Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not found a common mechanism of toxicity as to pyriproxyfen and any other substances and pyriproxyfen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that pyriproxyfen has a common mechanism of toxicity with other substances.

Safety factor for infants and children. The scientific information underpinning EPA's prior safety factor determination remains unchanged from the February 22, 2016 rulemaking (81 FR 8658) (FRL–9941–68). Therefore, EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety

factor for pyriproxyfen. See Unit III.D. of the February 22, 2016 rulemaking for a discussion of the Agency's rationale for that determination.

IV. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population adjusted dose (aPAD) and the 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 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.

Acute risk. An acute dietary risk assessment was not conducted because an acute endpoint could not be established.

Short-term and Intermediate-term risk. The short- and intermediate-term aggregate risk assessment remains unchanged from the 2017 draft human health risk assessment for *Registration Review.*

Chronic risk. In aggregating chronic risk, EPA considered background chronic dietary exposure (food + drinking water) and long-term residential combined (dermal + incidental oral) children 1 to <2 years old exposures from contact with small dogs treated with a pyriproxyfen collar. The chronic dietary (food + drinking water) exposures were estimated at 5.8% of the cPAD for the U.S. general population and 15% of the cPAD for the most highly exposed population subgroup (children 1–2 years old) and are below EPA's LOC (<100% cPAD). The total long-term dietary and residential aggregate (incidental oral + dermal) MOE is 320 for children 1 to <2 years. The total long-term dietary and residential aggregated (dermal) MOE is 1,000 for adults. As all these MOEs are greater than 100, the chronic aggregate risk is not of concern.

Aggregate cancer risk for U.S. population. Pyriproxyfen is classified as having no evidence for carcinogenicity to humans, based on the absence of evidence of carcinogenicity in male and female rats as well as in male and female mice. 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 pyriproxyfen residues. More detailed information on the subject action to establish tolerances in or on egg; poultry, fat; poultry, meat; and poultry, meat byproducts can be found at *http://www.regulations.gov* in the document entitled ''Pyriproxyfen. Human Health Risk Assessment for Establishment of Permanent Tolerances in Egg and Poultry Tissue and Amendment to Remove Restrictions Against the Presence of Animals in Poultry Houses During Premise Treatment,'' dated September 15, 2021. This document can be found in docket ID number EPA–HQ–OPP–2020–0512.

V. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the February 22, 2016 rulemaking (81 FR 8658) (FRL–9941–68).

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).

No Codex maximum residue limits (MRLs) have been established for residues of pyriproxyfen in/on the proposed commodities in this action. Canada has a default tolerance of 0.1 ppm on egg and poultry tissue.

C. Revisions to Petitioned-For Tolerances

The proposed amended use involves the establishment of permanent tolerances of pyriproxyfen in/on poultry egg and tissue. While OECD calculations procedures determined overall tolerances to be 0.03 ppm for poultry egg, muscle and liver, and 0.04 ppm for poultry fat, there is already an existing tolerance of 0.1 ppm under 40 CFR 180.510(a)(2) for FHE. EPA believes it would be inappropriate to set tolerances in/on poultry egg and tissue commodities below the currently established FHE tolerance. EPA is establishing tolerances of 0.1 ppm for residues in/on egg and poultry tissue under a new listing in the CFR (*i.e.,* 40 CFR 180.510 (a)(3)) for residues of pyriproxyfen and its metabolite 4′-OH-Pyr (free and conjugated), which would account for additional pyriproxyfen residues that could result from any subsequent FHE use of pyriproxyfen, as well as negligible residues on feed. For egg and poultry tissue, the proposed tolerance of 0.1 ppm is equal to the FHE tolerance and would be appropriate and protective.

Additionally, based upon review of the data supporting the petition as submitted by the petitioner, EPA recommends revisions to the commodity definitions in section G of the petition to specify poultry, fat; poultry, meat; and poultry, meat byproducts, rather than poultry, tissue.

VI. Conclusion

Tolerances are established for residues of pyriproxyfen, including its metabolites and degradates, in or on egg at 0.1 parts per million (ppm); poultry, fat at 0.1 ppm; poultry, meat at 0.1 ppm; and poultry, meat byproducts at 0.1 ppm.

VII. 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).

VIII. 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: November 5, 2021.

Catherine Aubee,

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 § 180.510, designate the table in paragraph (a)(1) as ''Table 1 to Paragraph (a)(1) and amend it by adding in alphabetical order the following commodities ''Egg''; ''Poultry, fat''; ''Poultry, meat''; and ''Poultry, meat byproducts'' to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Egg	0.1
* * * * *	
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts	0.1
* * * * *	

* * * * *

[FR Doc. 2021–24793 Filed 11–12–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0481; FRL–8918–01–OCSPP]

Methylorubrum populi Strain NLS0089; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Methylorubrum populi* strain NLS0089 in or on all food commodities when used in accordance with label directions and good agricultural practices. NewLeaf Symbiotics submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Methylorubrum populi* strain NLS0089 under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective November 15, 2021. Objections and requests for hearings must be received on or before January 14, 2022 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–2020–0481, is available at *https://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.

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FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

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- 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 40 CFR part 180 through the Office of the Federal