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.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Public Reading Room are 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: 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:

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 40 CFR part 180 through the Office of the Federal

Register's e-CFR site at *https://ecfr.federalregister.gov/current/title-40.*

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–2020–0481 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), although 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 delivery, 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 delivery, 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–2020–0481, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

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

II. Background

In the **Federal Register** of March 22, 2021 (86 FR 15162) (FRL–10021–44), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 0F8823) by NewLeaf Symbiotics, 1005 North Warson Rd., Ste. 102, St. Louis, MO 63132. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the fungicide *Methylorubrum populi* strain NLS0089 in or on all food commodities. That notice referenced a summary of the petition prepared by the petitioner NewLeaf Symbiotics and available in the docket via *https://www.regulations.gov.* No comments were received on the notice of filing.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption 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. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity.''

EPA evaluated the available toxicological and exposure data on *Methylorubrum populi* strain NLS0089 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled ''Revised Human Health Risk Assessment of *Methylorubrum populi* strain NLS0089, a New Active Ingredient, in TS601, a new End-Use Product Proposed for Registration, and an Associated Petition Requesting a Tolerance Exemption'' (*Methylorubrum populi* strain NLS0089 Human Health Assessment). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

The available data demonstrated that, with regard to humans, *Methylorubrum populi* strain NLS0089 is not anticipated to be toxic, pathogenic, or infective via any reasonably foreseeable route of exposure.

In an acute pulmonary toxicity/pathogenicity study, four test animals (one male rat and three female rats) treated with *Methylorubrum populi* strain NLS0089 died on days 2 or 3. Three of four of these test animals

exhibited irregular respiration before death, and, upon necropsy, were found to have red mottled lungs and/or fluid-filled intestines. Further, several of the surviving test animals treated with *Methylorubrum populi* strain NLS0089 exhibited abnormal clinical signs through day 4 (*e.g.,* irregular respiration or pale color) and/or had abnormal gross findings upon necropsy up to day 23 (*e.g.,* red mottled lungs and/or enlarged lymph nodes). Body weight and body weight gain were not adversely affected by treatment, and no abnormal clinical signs, mortalities, or gross necropsy findings were seen in the control animals (not treated or treated with inactivated *Methylorubrum populi* strain NLS0089). The abnormal clinical observations, mortalities, and abnormal necropsy findings are likely consistent with and attributed to factors such as anesthesia administration and test substance administration, which was higher than the recommended maximum hazard dose, via the intratracheal route. As a result, these findings are likely attributed to a combination of anesthesia effects and overdosing, which are not indicative of toxicity or relevant to pesticide exposure concerns when used according to label directions and good agricultural practices. Overall, this study established that *Methylorubrum populi* strain NLS0089 is not pathogenic or infective when administered intratracheally at a single dose of 2.93×10^9 colony-forming units (CFU) per test animal and demonstrated a pattern of clearance of *Methylorubrum populi* strain NLS0089 from the blood, cecum contents, and organs of the test animals.

In an acute injection toxicity/pathogenicity study, numerous test animals treated with *Methylorubrum populi* strain NLS0089 and one test animal treated with inactivated *Methylorubrum populi* strain NLS0089 had enlarged spleens upon necropsy up to day 22. There were no adverse effects of mortality, clinical signs, body weight, or body weight gain in any of the test groups. The abnormal necropsy findings likely reflect a physiological response to a blood-borne antigen rather than a toxic effect on the spleen due to the spleen's function of filtering blood of infectious agents. The assay was testing an artificial infection and most likely indicated lymphocytes producing antibodies reacting to the infection, which were filtered by the spleen causing an enlargement. It should be noted that signs of infection, *i.e.,* the spread of the microbial pest control agents (MPCA) across the blood/brain barrier or to other organs not involved with an immune response, were not noted, and there were no other signs of toxin production during exposure. Overall, this study established that *Methylorubrum populi* strain NLS0089 is not pathogenic or infective when administered intravenously at a single dose of 1.21×10^7 CFU per test animal and demonstrated a pattern of clearance of *Methylorubrum populi* strain NLS0089 from the blood, cecum contents, and organs of the test animals.

There may be some dietary and non-occupational exposures to residues of *Methylorubrum populi* strain NLS0089 when used in accordance with label directions and good agricultural practices, which exposures are only slightly more than environmental background levels for a short period of time after application. However, there is not a concern due to the lack of potential for adverse effects. Because there are no threshold levels of concern with the toxicity, pathogenicity, or infectivity of *Methylorubrum populi* strain NLS0089, EPA determined that no additional margin of safety is necessary to protect infants and children as part of the qualitative assessment conducted. Based upon its evaluation in the *Methylorubrum populi* strain NLS0089 Human Health Assessment, which concludes that there are no risks of concern from aggregate exposure to *Methylorubrum populi* strain NLS0089, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Methylorubrum populi* strain NLS0089.

B. Analytical Enforcement Methodology

An analytical method is not required for *Methylorubrum populi* strain NLS0089 because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of *Methylorubrum populi* strain NLS0089 in or on all food commodities when used in accordance with label directions and good agricultural practices.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. 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, 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 exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (15 U.S.C. 272 note).

V. 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 26, 2021.

Edward Messina,

Director, 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. Add § 180.1385 to subpart D to read as follows:

§ 180.1385 *Methylorubrum populi* strain NLS0089; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Methylorubrum populi* strain NLS0089 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2021–24794 Filed 11–12–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 3

Centers for Medicare & Medicaid Services

42 CFR Parts 402, 403, 411, 412, 422, 423, 460, 483, 488, and 493

Office of the Inspector General

42 CFR Part 1003

Office of the Secretary

45 CFR Parts 79, 93, 102, 147, 150, 155, 156, 158, and 160

Administration for Children and Families

45 CFR Part 303

RIN 0991–AC0

Adjustment of Civil Monetary Penalties for Inflation and the Annual Civil Monetary Penalties Inflation Adjustment for 2021

AGENCY: Office of the Assistant Secretary for Financial Resources, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule finalizes the provisions of the September 6, 2016 interim final rule that adjusts for inflation the maximum civil monetary penalty (CMP) amounts for all agencies within the Department of Health and Human Services (HHS) and updates certain agency-specific regulations. It also updates our required annual inflation-related increases to the CMP amounts in our regulations, under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015; adds references to new penalty authorities; and reflects technical changes to correct errors.

DATES:

Effective date: This final rule is effective November 15, 2021.

Applicability date: The adjusted civil monetary penalty amounts apply to penalties assessed on or after November 15, 2021, if the violation occurred on or after November 2, 2015.

FOR FURTHER INFORMATION CONTACT: David Dasher, Deputy Assistant Secretary, Office of Acquisitions, Office of the Assistant Secretary for Financial Resources, Room 536–H, Hubert Humphrey Building, 200 Independence Avenue SW, Washington DC 20201; 202–205–0706.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74) (the ''2015 Act'') amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 104 Stat. 890 (1990)), which is intended to improve the effectiveness of civil monetary penalties (CMPs) and to maintain the deterrent effect of such penalties, requires agencies to adjust the civil monetary penalties for inflation annually.

The Department of Health and Human Services (HHS) lists the CMP authorities and the amounts administered by all of its agencies in tabular form in 45 CFR 102.3, which was issued in an interim final rule published in the September 6, 2016, **Federal Register** (81 FR 61538). Annual adjustments were subsequently published on February 3, 2017 (82 FR 9175), October 11, 2018 (83 FR 51369), November 5, 2019 (84 FR 59549), and January 17, 2020 (85 FR 2869).

II. Provisions of the Final Rule

A. Finalization of the September 6, 2016 Interim Final Rule

In the September 6, 2016 **Federal Register** (81 FR 61538), HHS issued a department-wide interim final rule (IFR) titled ''Adjustment of Civil Monetary Penalties for Inflation'' that established new regulations at 45 CFR part 102 to adjust for inflation the maximum CMP amounts for the various CMP authorities for all agencies within the Department. HHS took this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (28 U.S.C. 2461 note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of the Bipartisan Budget Act of 2015, (Pub. L.114–74), enacted on November 2, 2015). In addition, the September 2016 IFR included updates to certain agency-specific regulations to reflect the new provisions governing the adjustment of civil monetary penalties for inflation in 45 CFR part 102.

One of the purposes of the Inflation Adjustment Act was to create a mechanism to allow for regular inflationary adjustments to federal civil monetary penalties. Section 2(b)(1) of the Inflation Adjustment Act. The 2015 amendments removed an inflation update exclusion that previously applied to the Social Security Act as