■ 2. Section 80.70 is amended by revising paragraph (j)(3) to read as follows:

§ 80.70 Covered areas.

* * * * *

(j) * * *

(3) Jefferson County, Kentucky;

* * * * *

[FR Doc. 2019–01320 Filed 2–6–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0163; FRL–9987–42]

Glycine betaine; 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 glycine betaine (CAS Reg. No. 107–43–7) when used as an inert ingredient (plant nutrient) in pesticide formulations applied to growing crops only. SciReg, Inc., on behalf of Fine Agrochemicals Ltd, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of glycine betaine.

DATES: This regulation is effective February 7, 2019. Objections and requests for hearings must be received on or before April 8, 2019, 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–2018–0163, 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 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–2018–0163 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 April 8, 2019. 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–2018–0163, 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. Petition for Exemption

In the **Federal Register** of May 18, 2018 (83 FR 23247) (FRL–9976–87), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11101) by SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192 on behalf of Fine Agrochemicals Ltd. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of glycine betaine (CAS Reg. No. 107–43–7) when used as an inert ingredient (plant nutrient) in pesticide formulations applied to growing crops. That document referenced a summary of the petition prepared by SciReg, Inc., on behalf of Fine Agrochemicals Ltd., the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as

carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for 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(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. The FFDCA requires EPA to consider the factors in subparagraphs (b)(2)(C) and (D) when making this safety determination. 21 U.S.C. 346a(c)(2)(B). 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 . . . .'' EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 glycine betaine including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with glycine betaine follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by glycine betaine as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Glycine betaine is naturally present in numerous foods including beets, spinach, grains, seafood, and eggs. Its presence has also been reported in bacteria, animals, and plants. It is produced in the human body from choline and the amino acid glycine and acts as a methyl group donor and osmolyte.

Glycine betaine has low acute oral toxicity. Acute dermal, inhalation, and dermal irritation studies for glycine betaine were not submitted. Glycine betaine was shown to be non-irritating to the eyes. In skin sensitization studies in mice, glycine betaine was not skin sensitizer. Although a dermal irritation study is not available, studies have shown that glycine betaine is found in human skin cell and sweat excreted from the body indicating that the chance for dermal irritation is minimal. In addition, a percutaneous dermal absorption study showed that only 0.1% of the applied dose permeated through the epidermis. This would make dermal toxicity unlikely.

Repeat dose oral toxicity studies on glycine betaine in rats include: Two 28-day studies, a 90-day study, and a combined chronic toxicity/carcinogenicity study. No adverse effects of treatment were seen in any of the studies up to the limit dose of 1000 Milligrams/kilograms/day (mg/kg/day). Some effects (*e.g.,* increased liver weights, hepatocellular vacuolation, and increased Gamma Glutamyl Transferase (GGT) levels) were seen at varying dose levels, but only at extremely high doses (≥4000 mg/kg/day) were these effects seen in combination and therefore, considered a potential effect of treatment. One of the 28-day rat oral toxicity studies included a 28-day reversal period where animals were fed the control diet and evaluated on day 56. The study showed that after the reversal period the liver weights were comparable to control and the vacuoles were gone.

The full study reports for studies referenced above were not available and therefore, the Agency could not determine if these effects (*e.g.,* increased liver weights, hepatocellular vacuolation, and increased GGT levels) were a true result of toxicity from the subject chemical or if they were within normal range of historical controls of the test animal or an effect of the excessive dosing. According to the summaries provided through the European Chemicals Agency (ECHA) database as part of the Registration, Evaluation, Authorization, and Restrictions of Chemical (REACH) program and the Cosmetic Ingredient Review (CIR) on betaine, betaine is tolerated at very high levels and its effects are reversible. This was also the finding of an article in *Food and Chemical Toxicology* which reviewed the two 28-day studies and the 90-day study. Although the study reviews did not treat these effects as adverse, and determined the NOAEL to be the highest dose tested in each case (4000–7143 mg/kg/day), in the absence of confirmatory data, the Agency has taken the conservative approach and treated these as an effect of treatment. The target organ in these studies appeared to be the liver.

While no developmental or reproductive studies were conducted with glycine betaine, it was seen to be beneficial in preventing neural tube defects and has been used in children as young as 24 days old as a treatment for homocystinuria. There was no evidence of carcinogenicity in any of the studies presented including the combined chronic/carcinogenicity study and studies on mutagenicity and cytotoxicity. In addition, no neuropathological changes or effects were reported in any of the studies. The Agency does not believe glycine betaine will be carcinogenic or neurotoxic.

B. Toxicological Points of Departure/Levels of Concern

Available toxicity studies on glycine betaine indicate that it has a very low acute, subchronic, and chronic toxicity.

No adverse effects were seen in any of the studies presented at the limit dose of 1000 mg/kg/day, effects seen above the limit dose level are not used for endpoint selection; therefore, no endpoint of concern has been selected for acute, subchronic, or chronic toxicity.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to glycine betaine, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from glycine betaine in food as follows:

Dietary exposure to glycine betaine may occur from eating foods naturally containing glycine betaine and foods treated with pesticide formulations containing glycine betaine as an inert ingredient. Because, at the limit dose, no endpoint of concern was identified, a quantitative dietary exposure assessment for glycine betaine was not conducted.

2. *Dietary exposure from drinking water.* Since a hazard endpoint of concern was not identified for the acute and chronic dietary assessment, a quantitative dietary exposure risk assessment for drinking water was not conducted, although exposures may be expected from use of pesticide formulations containing glycine betaine on food crops.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Glycine betaine may be used as inert ingredient in pesticide products that are registered for specific uses that may result in indoor or outdoor residential. Additional non-dietary exposure may occur from use of glycine betaine in pharmaceutical products and cosmetics. However, since there are no toxicological effects of concern at the limit dose in available studies, a quantitative assessment of residential (non-occupational) exposures and risks is not necessary.

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 glycine betaine to share a common mechanism of toxicity with any other substances, and glycine betaine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that glycine betaine 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://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) requires EPA to retain an additional tenfold margin of safety in the case of threshold effects 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. As noted in Unit IV.B., there is no indication of threshold effects being caused by glycine betaine at the limit dose. Therefore, due to the lack of any toxicological endpoints of concern at the limit dose, EPA is conducting a qualitative assessment of glycine betaine which does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on glycine betaine EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to glycine betaine under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.920 for residues of glycine betaine when used as an inert ingredient in pesticide formulations applied to growing crops, is safe under FFDCA section 408.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for glycine betaine (CAS Reg. No. 107–43–7) when used as an inert ingredient (plant nutrient) in pesticide formulations applied to growing crops only.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance 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); Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997); or 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 exemption 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: December 17, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticides.

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 § 180.920, add alphabetically the inert ingredient ''Glycine betaine (CAS Reg. No. 107–43–7)'' to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Glycine betaine (CAS Reg. No. 107–43–7)		Plant nutrient.
* * * * * * *		

[FR Doc. 2019–01307 Filed 2–6–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

46 CFR Part 506

[Docket No. 19–01]

RIN 3072–AC74

Inflation Adjustment of Civil Monetary Penalties

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Commission is publishing its adjustments to inflation annually, pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act). The 2015 Act requires that agencies adjust and publish their civil penalties by January 15 each year.

DATES: This rule is effective on February 7, 2019, and is applicable beginning January 15, 2019.

FOR FURTHER INFORMATION CONTACT: Tyler Wood, General Counsel, Federal Maritime Commission, 800 North Capitol Street NW, Room 1018, Washington, DC 20573; (202) 523–5740.

SUPPLEMENTARY INFORMATION: This rule adjusts the civil monetary penalties assessable by the Commission in accordance with the 2015 Act, which became effective on November 2, 2015, § 701 of Public Law 114–74. The 2015 Act further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), Public Law 101–410, 104 Stat. 890 (codified as amended at 28 U.S.C. 2461 note), in order to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect.

The 2015 Act requires agencies to adjust civil monetary penalties under their jurisdiction by January 15 each year, based on changes in the consumer price index (CPI–U) using data from October in the previous calendar year. On December 14, 2018, the Office of Management and Budget published guidance stating that the CPI–U multiplier for October 2018 is 1.02522.[1] In order to complete the adjustment for January 2019, the Commission must multiply the most recent civil penalty amounts in 46 CFR part 506.

Rulemaking Analyses and Notices

Notice and Effective Date

Adjustments under the FCPIAA, as amended by the 2015 Act, are not subject to the procedural rulemaking requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553), including the requirements for prior notice, an opportunity for comment, and a delay between the issuance of a final rule and its effective date.[2] As noted above, the 2015 Act requires that the Commission adjust its civil monetary penalties no later than January 15 of each year.

Congressional Review Act

The rule is not a ''major rule'' as defined by the Congressional Review Act, codified at 5 U.S.C. 801 *et seq.* The rule will not result in: (1) An annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies. 5 U.S.C. 804(2).

Regulatory Flexibility Act

The Regulatory Flexibility Act (codified as amended at 5 U.S.C. 601–612) provides that whenever an agency promulgates a final rule after being required to publish a notice of proposed rulemaking under the APA (5 U.S.C. 553), the agency must prepare and make available a final regulatory flexibility analysis (FRFA) describing the impact of the rule on small entities. 5 U.S.C. 604. As indicated above, this final rule is not subject to the APA's notice and comment requirements, and the Commission is not required to prepare

[1] Office of Management and Budget, M–19–04, Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, at 1 (Dec. 14, 2018) (M–19–04).

[2] FCPIAA section 4(b)(2); M–19–04 at 4.