TABLE 1 OF § 19.4—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. Code citation	Environmental statute	Statutory civil monetary penalties for violations that occur or occurred after November 2, 2015, where penalties are assessed on or after January 6, 2023	Statutory civil monetary penalties for violations that occurred after November 2, 2015, where penalties were assessed on or after January 12, 2022, but before January 6, 2023	Statutory civil monetary penalties, as enacted
42 U.S.C. 11045(c)(2)	EPCRA	27,018	25,076	10,000
42 U.S.C. 11045(d)(1)	EPCRA	67,544	62,689	25,000
42 U.S.C. 14304(a)(1)	MERCURY-CONTAINING AND RECHARGEABLE BATTERY MANAGEMENT ACT (BATTERY ACT).	18,827	17,474	10,000
42 U.S.C. 14304(g)	BATTERY ACT	18,827	17,474	10,000

[1] Note that 7 U.S.C. 136*l*(a)(2) contains three separate statutory maximum civil penalty provisions. The first mention of 1,000 and the 500 statutory maximum civil penalty amount were originally enacted in 1978 (Pub. L 95–396), and the second mention of 1,000 was enacted in 1972 (Pub. L. 92–516).

* * * * *

[FR Doc. 2022–28611 Filed 1–5–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0209; FRL–10495–01–OCSPP]

Extract of Caesalpinia Spinosa; 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 extract of *Caesalpinia spinosa* in or on all food commodities when used in accordance with good agricultural practices. Exponent, on behalf of Ag Chem Resources, LLC, 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 extract of *Caesalpinia spinosa* when used in accordance with this exemption.

DATES: This regulation is effective January 6, 2023. Objections and requests for hearings must be received on or before March 7, 2023, 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–2021–0209, 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 and the OPP docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1400; 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://www.ecfr.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–2021–0209 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 March 7, 2023. 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–2021–0209 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/contacts.html.*

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 and Statutory Findings

In the **Federal Register** of April 22, 2021 (86 FR 21317) (FRL–10022–59), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP0F8893) by Ag Chem Resources, LLC, 10120 Dutch Iris Drive, Bakersfield, CA 93311. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of extract of *Caesalpinia spinosa* in or on raw agricultural commodities and processed foods when used in accordance with good agricultural practices. That document referenced a summary of the petition prepared by the petitioner Ag Chem Resources, c/o Exponent, which is available in the docket, *https://www.regulations.gov* (EPA–HQ–OPP–2021–0209). There were no comments received in response to the notice of filing.

III. 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 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 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 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 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 harm to human health. If EPA is able to determine that a tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, 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 extract of *Caesalpinia spinosa* including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with extract of *Caesalpinia spinosa* follows.

IV. Toxicological Profile

Extract of *Caesalpinia spinosa* is a tannin-rich extract from the seed pods of Peruvian tara trees (*Caesalpinia spinosa*). There is a long history of safe exposure to tannins as these compounds are a part of the human diet and are naturally present in coffee and tea and nearly all vegetation, including in leaves, twigs, bark, wood, or fruit (U.S. EPA, 2006). Tannin compounds are found throughout the plant kingdom in forms ranging from simple phenols to macromolecules. Tannic acid is the macromolecule tannin compound found in *Caesalpinia spinosa* extract.

In conducting its hazard assessment for extract of *Caesalpinia spinosa,* EPA relied on the following data/information to satisfy the data requirements: (1) guideline acute toxicity studies; (2) guideline for the 90-day oral toxicity, prenatal developmental toxicity, and genetic toxicity studies; and (3) data waivers supported by information from open scientific literature in lieu of guideline studies for the 90-day dermal and 90-day inhalation data requirements. No adverse effects have been identified in the available data.

Extract of *Caesalpinia spinosa* has a low acute toxicity profile as evident by its toxicity Category IV classification for acute inhalation, acute dermal, acute oral toxicity, primary eye irritation, and primary dermal irritation. extract of *Caesalpinia spinosa* is not a dermal sensitizer.

To address the subchronic 90-day dermal data requirement, EPA granted a waiver based upon a weight of the evidence (WOE) approach as follows: (1) Extract of *Caesalpinia spinosa* is considered non-irritating to the skin, is not a dermal sensitizer, and is classified as Toxicity Category IV for acute dermal toxicity; (2) tannic acid is naturally occuring with a long history of exposure without adverse reactions seen in cosmetics and foods approved for use by the FDA; (3) the non-water component of the extract, tannin acid, has physiochemical properties that suggest a low probability for dermal penetration.

In terms of the 90 day-inhalation toxicity data requirement, EPA also granted a waiver based on the following: (1) tannic acid is naturally occurring with a long history of exposure with no adverse reactions reported; (2) tannic acid is approved for use in food by the FDA; (3) the physical and chemical properties of tannic acid (*e.g.,* the vapor pressure was too low to be reliably quantified for extract of *Caesalpinia spinosa* or tannic acid); (4) tannic acid is approved for inert ingredient (dispersing agent) use in pesticide products.

To address subchronic 90-day oral toxicity, data from a 90-day oral gavage study and a 4-week oral gavage study on rats with extract of *Caesalpinia spinosa* were conducted and found there were no adverse effects. The no-observed-effect-level (NOAEL) for both sexes was 3,500 mg/kg-bw/day and 3,000 mg/kg-bw/day, respectively, which were the highest doses tested in the studies. In addition, a 12-week dietary study on rats was provided using up to 800 mg/kg/day of tannic acid. In this study there were no significant changes in body weight, food intake, liver and kidney weights, gross pathology and histopathology observed.

For prenatal developmental and genetic toxicity, no maternal or developmental adverse treatment-related effects were observed. The NOAEL was greater than 3,500 mg/kg-bw/day, the highest dose level tested. In terms of mutagenicity, the active ingredient was determined to be non-mutagenic, and not genotoxic.

It is also relevant to the toxicological profile that ''tannin'' is approved for use as a direct human food additive as a boiler water additive under 21 CFR 173.310 and ''tannic acid'' is considered Generally Recognized as Safe (GRAS) when used as a flavoring agent, adjuvant, and pH control agent in baked goods, alcoholic beverages, beverage bases, gelatins, and frozen dairy desserts

per 21 CFR 184.1097. In terms of its use in pesticide formulations, tannin (including tannic acid) is exempt from the requirement of a tolerance as an inert ingredient in pesticide products when used as a dispersing agent applied to growing crops under 40 CFR 180.920. In addition to its widespread natural presence in foods, tannic acid is widely used in various cosmetic products such as soap, facial cleansers, masks, moisturizers, and serums. Further, tannic acid derived from plants is recognized as an animal feed additive for all species by the European Union of Feed Additives pursuant to Regulation EC No. 1831/2003.

A. Toxicological Points of Departure/ Levels of Concern

Based on the toxicological profile, EPA did not identify any toxicological endpoints of concern for assessing risk for this chemical.

B. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water.* Extract of *Caesalpinia spinosa* is a naturally occurring, tannin rich extract found in plants to which humans have been exposed through fruit, tea, coffee, feed grains, and vegetable consumption. As part of its qualitative risk assessment for extract of *Caesalpinia spinosa,* the Agency considered the potential for any additional dietary exposure to residues of extract of *Caesalpinia spinosa* from its proposed use as a nematicide on agricultural use sites. EPA concludes that such dietary (food and drinking water) exposures are likely to be negligible, as extract of *Caesalpinia spinosa* is readily biodegradable in the environment, potential residues of the substance are not anticipated on treated commodities at the time of consumption based on its physical chemical properties. Furthermore, residue data available for carrots and tomatoes show that when the proposed end-use product was applied according to labeled rates and methods, pesticide residues were indistinguishable from background levels. A quantitative dietary exposure assessment was not conducted because a toxicological endpoint for risk assessment was not identified.

2. *Residential exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure. There are no anticipated residential uses and significant residential exposure is not expected; therefore, residential handler and post-application risks of concern are not expected. Residential exposure may occur from non-pesticidal uses such as use in food commodities. However, inhalation exposure is not expected since tannins do not easily volatize because of their physical and chemical properties. A quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

3. *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 a tolerance exemption, 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.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to extract of *Caesalpinia spinosa* and any other substances, and this biopesticide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, EPA has not assumed that this active ingredient has 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 *https://www.epa.gov/pesticides/cumulative.*

C. Safety Factor for Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall retain 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 Food Quality Protection Act (FQPA) safety factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. An FQPA safety factor is not required at this time for extract of *Caesalpinia spinosa* because EPA is performing a qualitative dietary assessment based on negligible toxicological and exposure concerns.

D. Aggregate Risks

Based on the available data and information, the Agency has concluded that a qualitative aggregate risk assessment is appropriate to support this action, and that risks of concern are not anticipated from aggregate exposure to the extract of *Caesalpinia spinosa.* This conclusion is based on the low toxicity of the active ingredient, expected ready biodegradation in the environment, and existing natural levels present in foodstuffs. Anticipated dietary (food and drinking water) and bystander exposures are expected to be negligible, and there are no residential uses for the active ingredient. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found in the Memorandum entitled ''Product Chemistry Review and Human Health Risk Assessment for FIFRA Section 3 Registrations of the Manufacturing-Use Product, AgChem1, and the End-Use Product AgChem1–EP1, Containing extract of *Caesalpinia spinosa* (99.9%) as a New Active Ingredient''. This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

V. Determination of Safety for U.S. Population, Infants and Children

Based on the Agency's assessment, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of extract of *Caesalpinia spinosa.* Therefore, the establishment of an exemption from the requirement of a tolerance for residues of extract of *Caesalpinia spinosa* in or on all food commodities when used in accordance with good agricultural practices is safe under FFDCA section 408.

VI. 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.

VII. Conclusion

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR part 180 for residues of extract of *Caesalpinia spinosa* in or on all food commodities when used in accordance with good agricultural practices.

VIII. 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), 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 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).

IX. 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 21, 2022.

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 § 180.1396 to subpart D to read as follows:

§ 180.1396 Extract of *Caesalpinia spinosa;* exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for extract of *Caesalpinia spinosa* in or on all food commodities when used in accordance with good agricultural practices.

[FR Doc. 2023–00017 Filed 1–5–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1302

RIN 0970–AC90

Mitigating the Spread of COVID–19 in Head Start Programs

AGENCY: Office of Head Start (OHS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule removes the requirement for universal masking for all individuals ages 2 and older. This final rule requires that Head Start programs have an evidence-based COVID–19 mitigation policy, developed in consultation with their Health Services Advisory Committee. This final rule does not address the vaccination and testing requirement, which is still under review. The vaccine requirement remains in effect.

DATES: *Effective date:* This final rule is effective January 6, 2023.

Compliance date: The compliance date for the evidence-based COVID–19 mitigation policy specified at § 1302.47(b)(9) is, March 7, 2023. For more information, *see* Implementation Timeframe.

FOR FURTHER INFORMATION CONTACT: Kate Troy, OHS, at *HeadStart@eclkc.info* or 1–866–763–6481. Deaf and hearing-impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 between 8 a.m. and 7 p.m. Eastern Standard Time.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

(1) Purpose of the Regulatory Action

(a) *The need for the regulatory action and how the action will meet that need:* The purpose of this regulatory action is to finalize, with modification, the Interim Final Rule with Comment Period (IFC), *Vaccine and Mask Requirements to Mitigate the Spread of COVID–19 in Head Start Programs,* which ACF issued on November 30, 2021 (86 FR 68052). This final rule takes into consideration the more than 1,700 public comments received on masking during the comment period, the most up to date data available on COVID–19, and knowledge gained through research on the transmission and effects of SARS–CoV–2 to establish a policy that prioritizes the health and safety of children served by the federal Head Start program, their families, and the program's staff while also adapting to the realities of evolving COVID–19 conditions. In brief, this final rule: