

Issued on August 4, 2025.

Peter A. White,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2025–14933 Filed 8–5–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2021–C–0522]

Listing of Color Additives Exempt From Certification; Gardenia (Genipin) Blue; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting the order entitled “Listing of Color Additives Exempt from Certification; Gardenia (Genipin) Blue”. In the order, FDA amended the color additive regulations to provide for the safe use of gardenia (genipin) blue in various foods, at levels consistent with good manufacturing practice (GMP). The order inadvertently misstated the methanol specification. This document corrects that error.

DATES: Effective August 29, 2025.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Office of Pre-market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2710; or Deirdre Jurand, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In FR Doc. 2025–13175, appearing on page 31586 in the **Federal Register** of Tuesday, July 15, 2025, the following corrections are made:

1. In the **SUPPLEMENTARY INFORMATION** section, in subsection II: Background, on page 31588, in the first column, in the middle of the first full paragraph, “6 mg/kg (6 ppm)” is corrected to read “300 mg/kg (300 ppm)”.

§ 73.168 [Corrected]

2. On page 31590, in the second column, in § 73.168, in paragraph (b)(3), “Methanol, not more than 6 mg/kg (6 ppm).” is corrected to read “Methanol, not more than 300 mg/kg (300 ppm).”

Dated: August 1, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14905 Filed 8–5–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2025–0473]

Special Local Regulation; Marine Events Within the Eleventh Coast Guard District—Swim for Special Operations Forces.

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation on the waters of San Diego Bay, CA, during the Swim for Special Operations Forces on September 13, 2025. This special local regulation is necessary to provide for the safety of the participants, crew, sponsor vessels of the event, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from entering, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1101 for the location described in Item 16 in table 1 to § 100.1101, will be enforced from 7:30 a.m. until Noon on September 13, 2025.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Shelley Turner, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the location identified in Item No. 16 in table 1 to § 100.1101, from 7:30 a.m. until Noon on September 13, 2025, for the Swim for Special Operations Forces in San Diego Bay, CA. This action is being taken to provide for the safety of life on the navigable waterways during the event. Our regulation for recurring marine events in the San Diego Captain of the Port Zone, § 100.1101, Item No. 16 in table 1 to § 100.1101, specifies the location of the regulated area for the

Swim for Special Operations Forces, which encompasses portions of San Diego Bay. Under the provisions of § 100.1101, persons and vessels are prohibited from entering, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

R.C. Tucker,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2025–14899 Filed 8–5–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–1102]

RIN 1625–AA11

Regulated Navigation Area; Ludington Harbor Channel and Pere Marquette Lake, Ludington, MI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a regulated navigation area to control vessel movement for certain waters of Lake Michigan, the Ludington Harbor Channel, and Pere Marquette Lake in Ludington, MI. This action is necessary to provide for the safety of life, environment, and property on these navigable waters due to hazardous conditions resulting from increased vessel traffic congestion.

DATES: This rule is effective without actual notice August 6, 2025. For the purposes of enforcement, actual notice will be used from 01 Aug 2025 until August 6, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–1102 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call

or email Lieutenant Commander Jessica Anderson, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414-216-8428, email d09-smb-seclakemichigan-wwm@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
OMB Office of Management and Budget
RNA Regulated Navigation Area
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

Beginning in August 2022, the Coast Guard received notice that sporadic high concentrations of vessels operating in the vicinity of the narrow waters of the Ludington Harbor Channel and Pere Marquette Lake in Ludington, MI, were creating hazardous navigation conditions for larger vessels transiting the area. Of particular concern, large commercial vessels were forced to take immediate action on several occasions to avoid imminent collision with these highly concentrated vessels. High concentration of vessels were not always present, but arose sporadically, primarily in connection with fishing seasons. Similar concerns were brought to the Coast Guard in the summer and fall of 2023 and 2024. In response, on April 22, 2025, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled, “Regulated Navigation Area; Ludington Harbor Channel and Pere Marquette Lake, Ludington, MI” (FR Doc. 2025-06868). There we stated why we issued the NPRM and invited comments on the proposed regulated navigation area. During the comment period, which ended June 23, 2025, we received 15 comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule is impracticable because immediate action is needed to respond to the potential safety hazards associated with an anticipated salmon migration into the regulated area on or about August 1, 2025 and subsequent hazardous levels of vessel congestion due to increased salmon fishing vessel activity in the regulated area.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority in 46 U.S.C. 70034.

The Great Lakes District Commander has determined that a Regulated Navigation Area (RNA) is necessary to address safety concerns due to hazardous levels of vessel traffic congestion in the Ludington Harbor Channel and Pere Marquette Lake in Ludington, MI. The goal is to prevent loss of life, vessel collisions and groundings, environmental damage, and loss of property resulting from conflicts between varied users of these navigable waterways. These regulations are intended to encompass fishing vessels, pleasure craft, ferries, tow boats, deep draft vessels, and other commercial vessel traffic. This regulation is necessary due to a significant increase in risks to safety and hazardous conditions due to high volumes of traffic, combined with a unique layout of the navigable waters and relatively narrow channel, requiring additional means to protect waterways users as normal navigation rules are not sufficient.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received 15 comments on our NPRM published April 22, 2025. Of those comments, 6 were in support of the RNA as written and the Coast Guard appreciates the positive feedback and support for this endeavor to keep waterways safe for all waterways users.

There were 9 comments which require more detailed response. The first comment supported specific rules being placed pertaining to crowded waterways and the local ferry but was not in support of temporary rules. To clarify, this is a permanent rule, only the enforcement periods will be temporary. This rule allows the Captain of the Port, with input from local law enforcement authorities, to activate and enforce the RNA while conditions warrant. Unlike a temporary rule, the Coast Guard will have the ability to activate and enforce the RNA at any time during the entire year but will only do so when conditions deem it necessary. The Coast Guard appreciates the input.

The second comment agreed that rules providing safety are appropriate but cautioned against ambiguity. This comment highlighted the challenge in interpreting the proposed distances. The Coast Guard and our partners are dedicated to the safety of all waterway users and are taking a proactive approach to ensure safety for all parties. Discretion will be used during the enforcement periods of the RNA. These distances provide federal and local law enforcement with greater enforcement capability by establishing more specific

standards than current rules allow. A prudent mariner will operate at greater distances than the distances listed in the rule. The Coast Guard, in conjunction with local authorities, will provide educational materials and outreach as the RNA goes into effect. The Coast Guard and its state and local partners’ goal is to promote safety by deterring unsafe acts. During enforcement of the RNA, operating at less than the distances listed may result in enforcement action. The Coast Guard urges all mariners to maintain situational awareness and abide by all navigational rules.

The third comment stated that the RNA establishes a precedent that a larger vessel is right in all interactions. That is not correct. The RNA only establishes minimum distances to be maintained from vessels 100 feet or longer when conditions warrant. These requirements recognize that larger vessels in constricted waters with high traffic density are less able to maneuver quickly to avoid another vessel. It does not grant vessels larger than 100 feet any exemption from the Inland Navigation Rules, or the need for these vessels to operate in a prudent manner. This RNA does not grant any vessel any preference or deviation from the Rules of the Road.

The fourth comment expressed concerns surrounding visitors to the Ludington and Pere Marquette area being unaware of the rules. The Coast Guard, in conjunction with local partners, will be providing educational and informative materials for the proposed RNA once the final rule has been published.

The fifth comment inquired as to the enforcement of Rule 9 of the COLREGS. By implementing this RNA, the Coast Guard is not stating that Rule 9 does not apply to the regulated area. However, this RNA provides greater clarity to mariners regarding the specific procedures to follow during periods of the rule’s enforcement in order to ensure safety of life, environment, and property on these navigable waters. The aim of this RNA is to minimally impact the usage of the waterway for all waterway users as all mariners, both recreational and commercial, have equal usage of a Federal Waterway.

The sixth comment stated that the problem is sporadic high concentrations of vessels operating in the vicinity of narrow waters of the Ludington Harbor Channel and Pere Marquette Lake but that the proffered solution leaves full discretion to the COTP as to when the concentration of vessels becomes high enough to activate the regulation. The commentor suggests that a minimum number of vessels should automatically

trigger activation of the regulation. The commentor also stated that the minimum distances from vessels greater than 100' in length seem impossible to meet and requested more clarity on how information will be distributed. All vessels are to comply with established Navigation Rules. This RNA, when activated, establishes minimum distances for all mariners that must be kept from all vessels greater than 100 feet in length, not just commercial vessels. By maintaining the specified distances, vessels will not be transiting in closer proximity to vessels that are 100 feet in length. The Coast Guard will provide educational and informative broadcasts as well as provide outreach with the Harbormaster of Ludington and other enforcement authorities.

The seventh comment requested specific coordinates for the rule. As the rule is written, it would encompass an arc 1,000 yards from the Ludington, Michigan harbor entrance. GPS coordinates can be extrapolated from that arc. The Coast Guard will continue to work with our federal Partners to ensure clarity and compliance.

The eighth comment stated salmon began returning to Pere Marquette in the late 1960s and that there has been seasonal, sporadic congestion ever since without the need for additional federal action. The comment expressed concerns with electronic anchoring, reduction in Coast Guard presence, and increased commercial traffic. The commentor desired increased Coast Guard presence and clarity as to who will declare this regulation effective in times of congestion. The commentor also expressed concerns with the proposed distances in that they should allow for boats to remain in the channel at a safe distance while commercial traffic is passing. The Coast Guard is committed to the safety of the waterway and all waterways users. The Coast Guard maintains search and rescue as well as law enforcement coverage through a layered system. There is not a current rule which adequately addressed the hazards described in this comment. This rule allows the Coast Guard to take a preventative approach to mitigate close quarters situations and risk of collision within the proposed area. The Coast Guard, as well as the Harbormaster of Ludington, have directly observed the hazardous conditions this rule is intended to address. In determining whether to activate the RNA's requirements, the Captain of the Port will likely seek input from Coast Guard Station Manistee which provides assets to the Coast Guard's Forward Operating Location in Ludington along with local authorities

to determine if the waterway congestion is compromising the safety of navigation of vessels. This RNA does not preclude vessels from being in the channel while vessels greater than 100' pass through as long as they abide by the navigation rules.

The ninth comment stated that skill and understanding of the COLREGS by recreational fisherman is the issue. The commentor requested for recreational fishing vessels to be banned from the area permanently and for the area to be extended to 1,000 yards in all directions for all vessels greater than 26'. The Coast Guard is committed to maintaining a safe and transitable waterway for all mariners and is seeking to establish a rule that has the most minimal, but effective, results for all who seek to use this waterway.

The Coast Guard appreciates all of the comments that were received, both in favor and those requesting further clarification. Taking into consideration these comments and our responses, there is one change to the regulatory text of this rule from the proposed rule in the NPRM. The words "at least" were added in paragraph (d)(1) to state "Vessels and all waterways users must maintain a distance of at least 440 yards from the bow, 100 yards from the stern, and 35 yards from the port and starboard side of any vessel greater than 100 feet in length transiting through the regulated navigation area as described in paragraph (a) of this section."

This rule establishes a regulated navigation area which would be enforced only when hazardous levels of vessel traffic congestion ("Congestion") exist. Operations potentially creating Congestion include, but are not limited to, vessels engaged in fishing, recreational fishing derbies, regattas, or permitted marine events. The Captain of the Port, Sector Lake Michigan ("COTP") will determine when Congestion exists and will notify the public via Broadcast Notice to Mariners and other comparable public notice and will coordinate and inform the harbormaster of Ludington before enforcement of the Regulated Navigation Area. When Congestion exists, vessels and all waterways users, with the exception of Federal or State entities operating in official capacity, would be required to maintain a distance of at least 440 yards from the bow, 100 yards from the stern, and 35 yards from the port and starboard side of any commercial or recreational vessels greater than 100 feet in length transiting into or out of the Ludington Harbor Channel, starting at 1,000 yards outside the Ludington Harbor entrance and encompassing all navigable

waterways within the Ludington Harbor Channel and Pere Marquette Lake.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) has not designated this rule a "significant regulatory action," under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it.

This regulatory action determination is based on the characteristics of the regulated navigation area. The proposed rule is expected to place minimal restrictions on vessel movement and is designed to minimize impact on navigable waters. Vessels may still transit through the regulated navigation area and the impact will be short in duration.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement

Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a

State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a regulated navigation area which would be enforced only when Congestion exists. During this period of enforcement, vessels would be permitted to operate, albeit it with limited navigation restrictions when large commercial vessels are transiting the regulated waters. Accordingly, it is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons stated in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

- 2. Add § 165.972 to read as follows:

§ 165.972 Regulated Navigation Area; Ludington Harbor Channel and Pere Marquette Lake, Ludington, Michigan

(a) *Location.* The following area is a regulated navigation area: All navigable waters of the Ludington Harbor Channel and Pere Marquette Lake, from surface to bottom, as well as navigable waters of

Lake Michigan within 1,000 yards of the Ludington, Michigan harbor entrance.

(b) *Definitions.* As used in this section:

(1) *Vessels engaged in fishing* are as identified in the definition found in Rule 3 of the International Regulations for Prevention of Collisions at Sea, 1972, (72 COLREGS), found in appendix A, part 81 of this chapter.

(2) *Hazardous levels of vessel traffic congestion* are as defined at the time by the Captain of the Port or a designated representative. Operations potentially creating hazardous levels of vessel traffic congestion include, but are not limited to, vessels engaged in commercial or recreational fishing, pleasure craft, tow boats, other commercial vessel traffic, recreational fishing derbies, regattas, permitted marine events, or any other condition creating a high concentration of vessels in the regulated navigation area.

(3) *Designated representative* of the Captain of the Port is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port to act on his or her behalf.

(4) *Ludington Harbor entrance* is defined as the waters between the westernmost point of the Ludington Harbor break walls as marked by the Ludington North Breakwater Light (LLNR 18530) and Ludington Harbor South Breakwater Light (LLNR 18555).

(c) *Rules of the Road.* Nothing in this section shall be construed as relieving any party from their responsibility to comply with applicable rules set forth in the 72 COLREGS.

(d) *Regulations.* The provisions under this paragraph apply only when imposed in specific locations by the Captain of the Port or a designated representative. They are intended to enhance vessel traffic safety during periods and in locations where hazardous levels of vessel traffic congestion are deemed to exist by the Captain of the Port or a designated representative. When hazardous levels of vessel traffic congestion are determined to exist by the Captain of the Port or a designated representative per paragraph (b)(2) of this section, the Captain of the Port or designated representative will issue a Broadcast Notice to Mariners and other comparable public notice and will coordinate and inform the harbormaster of Ludington, notifying the public of the period and location of enforcement prior to enforcing the provisions under this paragraph.

(1) Vessels and all waterways users must maintain a distance of at least 440 yards from the bow, 100 yards from the stern, and 35 yards from the port and

starboard side of any vessel greater than 100 feet in length transiting through the regulated navigation area as described in paragraph (a) of this section.

(2) Federal, State, or local entities operating in official capacity are excepted from paragraph (d).

(3) In an emergency, the master, pilot, or person directing the movement of the vessel may deviate from this section to the extent necessary to avoid endangering persons, property, or the environment, and shall report the deviation to The United States Coast Guard via VHF channel 16 as soon as possible.

(4) Violations of this rule should be reported to the Captain of the Port Sector Lake Michigan, at (414) 747-7182 or on VHF-Channel 16. Vessels or persons in violation of this rule may be subject to the civil and/or criminal penalties set forth in 46 U.S.C. 70036.

Dated: August 1, 2025.

M.I. Kuperman,

*Captain, U.S. Coast Guard, Acting
Commander, Great Lakes District.*

[FR Doc. 2025-14884 Filed 8-5-25; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA-HQ-OPP-2024-0293; FRL-12818-01-
OCSPP]

Bacillus thuringiensis Cry1A.2 and Cry1B.2 Proteins; Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Cry1A.2 and Cry1B.2 proteins (hereafter Cry1A.2 and Cry1B.2 proteins) in or on the food and feed commodities of soybean when used as plant-incorporated protectants (PIP) in soybean. Bayer CropScience LP submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting these exemptions. This regulation eliminates the need to establish a maximum permissible level for residues of these pesticides when used in accordance with the terms of the exemption.

DATES: This regulation is effective on August 6, 2025. Objections and requests for hearings must be received on or before October 6, 2025, and must be filed in accordance with the instructions

provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2024-0293, is available at <http://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Shannon Borges, 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. Executive Summary

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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) 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." FFDCA section 408(c)(2)(A)(ii) 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, among other things, "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

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. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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-2024-0293 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 October 6, 2025.

EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. 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; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a