within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See CAA section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting, Recordkeeping requirements, and Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: October 20, 2025.

Cheree D. Peterson,

Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.282 is amended by adding paragraph (q) to read as follows:

§ 52.282 Control strategy and regulations: Ozone.

* * * * *

(q) *Determination of attainment by the attainment date.* Effective December 1, 2025. The EPA has determined that the Mariposa County Moderate nonattainment area in California attained the 2015 8-hour ozone National Ambient Air Quality Standards (NAAQS) by the applicable attainment date of August 3, 2024, based upon complete, quality-assured and certified data for the calendar years 2021–2023.

[FR Doc. 2025–19714 Filed 10–29–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0157; FRL–13031–01–OCSPP]

ASFBIOF01-02 Polypeptide; Exemption From the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of ASFBIOF01-02 polypeptide in or on all food and feed commodities if used according to the label and good agricultural practices. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), Biotalys NV submitted a petition to EPA requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this pesticide when used in accordance with the terms of the exemption.

DATES: This regulation is effective October 30, 2025. Objections and requests for hearings must be received on or before December 29, 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–2021–0157, 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) 566–1200; 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. 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. 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 the docket ID number EPA–HQ–OPP–2021–0157 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 December 29, 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%20-%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 person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf.*

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 at *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. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned for Exemption

In the **Federal Register** of March 22, 2021 (86 FR 15162) (FRL–10021–44), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F8895) by Biotalys NV (Technologiepark 94, 9052 Ghent, Belgium, c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of ASFBIOF01-02 polypeptide in or on all food commodities. That document referenced a summary of the petition prepared by the petitioner Biotalys NV, which is available in the docket.

There were no comments received in response to the notice of filing.

III. Final Tolerance Actions

A. EPA's Safety Determination

EPA evaluated the available toxicological and exposure data on ASFBIOF01–02 polypeptide (hereafter ASFBIOF01–02) 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 the EPA relied and its risk assessment based on those data can be found within the document entitled ''Product Characterization and Human Health Risk Assessment for a FIFRA Section 3 Registration Request for the New Active Ingredient ASFBIOF01–02, the Manufacturing Use Product 'ASFBIOF01–02 AGROBODY biofungicide,' and the End Use Product 'EVOCA,' as well as an Associated Petition to Exempt Residues of ASFBIOF01–02 from the Requirement of a Tolerance per FFDCA Section 408'' (Human Health Risk Assessment). This document, as well as other relevant information, are available in docket number EPA–HQ–OPP–2021–0157.

Products formulated with ASFBIOF01–02 are intended for use as fungicides to control or suppress pre-harvest and post-harvest crop diseases on food and non-food crops. The active ingredient ASFBIOF01–02 is an antigen binding fragment of an antibody (*i.e.,* protein) that recognizes specific components in the fungal cell membrane. Binding of sufficient amounts of ASFBIOF01–02 to the cell membrane of the growing fungus results in the disruption of the cell integrity, leading to lysis and fungal death.

Dietary exposure to ASFBIOF01–02 may result from the consumption of treated crops, although such exposure is likely to be limited by the expected lability of the protein in the environment. The sole end-use product currently proposed for registration is a broad-spectrum sprayable fungicide proposed for the control/suppression of pre-harvest plant and post-harvest crop diseases on both food and non-food crops. ASFBIOF01–02 is a protein, which is a biological substance that is subject to the processes of biodegradation and decay through mechanisms such as photodegradation, hydrolysis, and active degradation through microbial activity in the environment. As such, ASFBIOF01–02 is not expected to accumulate in the environment but rather be converted into its amino acid constituent through the aforementioned biotic and abiotic processes. Similarly, the likelihood of ASFBIOF01–02 exposure through drinking water is expected to be low given the protein's environmental lability. Furthermore, stability in aquatic environments, including municipal water treatment plants, is not expected.

Based on a weight-of-evidence approach, considering all available hazard and exposure data for ASFBIOF01–02, the agency conducted a qualitative dietary risk assessment. Dietary risk from ASFBIOF01–02 is considered negligible for the following reasons: (1) submitted acute oral toxicity (EPA Toxicity Category IV) and subchronic oral toxicity studies demonstrate a low toxicity profile for ASFBIOF01–02; (2) the protein is readily digested in simulated gastric and intestinal fluids, indicating a low likelihood of allergenicity; (3) bioinformatic (*in silico*) analysis with the ASFBIOF01–02 amino acid sequence showed that there is a low likelihood that the antibody fragment exhibits cross-reactivity with known or putative allergens; and (4) the expected lability of the ASFBIOF01–02 protein in the environment. There are no proposed residential uses for the product formulated with ASFBIOF01–02; therefore, a residential handler and post-application exposure and risk assessment has not been conducted.

Although FFDCA section 408(b)(2)(C) provides for an additional tenfold margin of safety for infants and children in the case of threshold effects, EPA has determined that there are no such effects due to the lack of toxicity of ASFBIOF01–02. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

B. Analytical Enforcement Methodology

An analytical method is not required for ASFBIOF01–02 since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Conclusion

Based upon its evaluation in the Human Health Risk Assessment, EPA concludes that use of ASFBIOF01–02 will not result in unreasonable adverse health effects to humans and 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 ASFBIOF01–02. Therefore, EPA is finalizing the tolerance exemption that was petitioned for by Biotalys NV (PP 1F8895). An exemption is established for residues of ASFBIOF01–02 in or on all food commodities.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA, 44 U.S.C. 3501 *et seq.,* because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local or Tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects 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.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2021 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which 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 . . .'' (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific review documents, located in the applicable docket at *https://www.regulations.gov.*

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of Congress and to the Comptroller General of the United States. 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 15, 2025.

Edward Messina,

Director, Office of Pesticide Programs.

For the reasons set forth 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 § 180.1421 to subpart D to read as follows:

§ 180.1421 ASFBIOF01–02 polypeptide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of ASFBIOF01–02 polypeptide in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2025–19712 Filed 10–29–25; 8:45 am]

BILLING CODE 6560–50–P