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List of Subjects in 40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Michael S. Regan,

Administrator.

For reasons stated in the preamble, part 51 of chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

Subpart F—Procedural Requirements

■ 2. Section 51.100 is amended by revising paragraph (s)(1) introductory text to read as follows:

§ 51.100 Definitions.

* * * * *

(s) * * *

(1) This includes any such organic compound other than the following, which have been determined to have negligible photochemical reactivity: methane; ethane; methylene chloride (dichloromethane); 1,1,1-trichloroethane (methyl chloroform); 1,1,2-trichloro-1,2,2-trifluoroethane (CFC–113); trichlorofluoromethane (CFC–11); dichlorodifluoromethane (CFC–12); chlorodifluoromethane (HCFC–22); trifluoromethane (HFC–23); 1,2-dichloro 1,1,2,2-tetrafluoroethane (CFC–114); chloropentafluoroethane (CFC–115); 1,1,1-trifluoro 2,2-dichloroethane (HCFC–123); 1,1,1,2-tetrafluoroethane (HFC–134a); 1,1-dichloro 1-fluoroethane (HCFC–141b); 1-chloro 1,1-difluoroethane (HCFC–142b); 2-chloro-1,1,1,2-tetrafluoroethane (HCFC–124); pentafluoroethane (HFC–125); 1,1,2,2-tetrafluoroethane (HFC–134); 1,1,1-trifluoroethane (HFC–143a); 1,1-difluoroethane (HFC–152a); parachlorobenzotrifluoride (PCBTF); cyclic, branched, or linear completely methylated siloxanes; acetone; perchloroethylene (tetrachloroethylene); 3,3-dichloro-1,1,1,2,2-pentafluoropropane (HCFC–225ca); 1,3-dichloro-1,1,2,2,3-pentafluoropropane (HCFC–225cb); 1,1,1,2,3,4,4,5,5,5-decafluoropentane (HFC 43–10mee); difluoromethane (HFC–32); ethylfluoride (HFC–161); 1,1,1,3,3,3-hexafluoropropane (HFC–236fa); 1,1,2,2,3-pentafluoropropane (HFC–245ca); 1,1,2,3,3-pentafluoropropane (HFC–245ea); 1,1,1,2,3-pentafluoropropane (HFC–245eb); 1,1,1,3,3-pentafluoropropane (HFC–245fa); 1,1,1,2,3,3-hexafluoropropane (HFC–236ea); 1,1,1,3,3-pentafluorobutane (HFC–365mfc); chlorofluoromethane (HCFC–31); 1 chloro-1-fluoroethane (HCFC–151a); 1,2-dichloro-1,1,2-trifluoroethane (HCFC–123a); 1,1,1,2,2,3,3,4,4-nonafluoro-4-methoxy-butane ($C_4F_9OCH_3$ or HFE–7100); 2-(difluoromethoxymethyl)-1,1,1,2,3,3,3-heptafluoropropane ($(CF_3)_2CFCF_2OCH_3$); 1-ethoxy-1,1,2,2,3,3,4,4,4-nonafluorobutane ($C_4F_9OC_2H_5$ or HFE–7200); 2-(ethoxydifluoromethyl)-1,1,1,2,3,3,3-heptafluoropropane ($(CF_3)_2CFCF_2OC_2H_5$); methyl acetate; 1,1,1,2,2,3,3-heptafluoro-3-methoxy-propane (n-C3F7OCH3, HFE–7000); 3-ethoxy- 1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl) hexane (HFE–7500); 1,1,1,2,3,3,3-heptafluoropropane (HFC 227ea); methyl formate (HCOOCH3); 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-trifluoromethyl-pentane (HFE–7300); propylene carbonate; dimethyl carbonate; *trans*-1,3,3,3-tetrafluoropropene; HCF_2OCF_2H (HFE–134); $HCF_2OCF_2OCF_2H$ (HFE–236cal2); $HCF_2OCF_2CF_2OCF_2H$ (HFE–338pcc13); $HCF_2OCF_2OCF_2CF_2OCF_2H$ (H-Galden 1040x or H-Galden ZT 130 (or 150 or 180)); *trans* 1-chloro-3,3,3-trifluoroprop-1-ene; 2,3,3,3-tetrafluoropropene; 2-amino-2-methyl-1-propanol; t-butyl acetate; 1,1,2,2-Tetrafluoro-1-(2,2,2-trifluoroethoxy) ethane; *cis*-1,1,1,4,4,4-hexafluorobut-2-ene (HFO–1336mzz-Z); trans-1,1,1,4,4,4-hexafluorobut-2-ene *(HFO–1336mzz(E));* and perfluorocarbon compounds which fall into these classes:

* * * * *

[FR Doc. 2023–02384 Filed 2–7–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0396; FRL–10572–01–OCSPP]

Peptide Derived From Harpin Protein; 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 Peptide Derived from Harpin Protein (PDHP) 25279 in or on all food commodities when used in accordance with label directions and good agricultural practices. Plant Health Care Inc., 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 PDHP 25279 under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective February 8, 2023. Objections and requests for hearings must be received on or before April 10, 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–2021–0396, 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 20004. 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 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–2021–0396 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 10, 2023. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although EPA strongly encourages those interested in submitting objections or a hearing request to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), *https://www.epa.gov/sites//default/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.* At this time, because of the COVID–19 pandemic, the judges and staff of the Office of Administrative Law Judges are working remotely and not able to accept filings or correspondence by courier, personal delivery, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf.*

Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is impossible for a person to submit documents electronically or receive service electronically, *e.g.,* the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564–6281. If a person is without access to a computer and must file documents by U.S. Mail, the person shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0396, 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/ets/send-comments-epa-dockets.*

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

II. Background

In the **Federal Register** of June 17, 2022 (87 FR 36438) (FRL–9929–01), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 1F8901) by Plant Health Care Inc., 2626 Glenwood Ave., Suite 350, Raleigh, NC 27608. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of fungicide PDHP 25279 in or on growing crops or seeds. That notice referenced a summary of the petition prepared by the petitioner Plant Health Care Inc., and available in the docket via *https://www.regulations.gov.* EPA received one comment on the notice of filing. EPA's response to this comment is discussed in Unit III.C.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a

tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity.''

EPA evaluated the available toxicological and exposure data on PDHP 25279 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled ''Human Health Risk Assessment, Review of Product Characterization and Manufacturing Processes of the New End-Use Product PHC 25279 Containing the New Active Ingredient Harpin Protein PDHP 25279. Data was Provided in Support of a FIFRA Section 3 Registration and Establishment of a Permanent Tolerance Exemption'' (Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Available data have demonstrated that, with regard to humans, Peptide Derived from Harpin Protein (PDHP) 25279 is not anticipated to be toxic or allergenic via any reasonably foreseeable route of exposure. The active ingredient in PDHP 25279 is a 28 amino acid peptide derived from the harpinW protein found in the phytopathogenic bacterium *Erwinia amylovora,* a plant pathogen responsible for causing fire blight in plants such as apple, pear, and raspberry. PDHP 25279 is a third-generation PDHP that does not directly affect the target pest. Instead, the mode of action for PDHP 25279 is proposed to be through the induction of natural defense mechanisms in the plant by way of salicylic acid (SA) and ethylene/jasmonic acid-dependent signaling, which in turn activate the ''hypersensitive response'' (HR) and ultimately elicit systemic acquired resistance in the plant. HR is characterized as rapid, localized cell death in plant tissue after infiltration of the peptide into the intercellular spaces of plant leaves. This reaction initiates a complex set of metabolic responses in the treated plant, causing systemic gene expression and eliciting a plant's natural growth and defense system, which results in enhanced resistance of the plant to fungal and bacterial diseases.

The Agency has concluded that any potential dietary risk from the use of PDHP 25279 to human health is considered negligible for the following reasons: (1) PDHP 25279 was found to have low toxicity via the oral route of exposure, did not show any homology to known or putative allergens, and is rapidly degraded in simulated gastric fluids. The submitted mammalian toxicity studies and the studies that are bridged from similar already registered harpin proteins to support the tolerance exemption for the active ingredient PDHP 25279 are summarized with their classifications in the Human Health Risk Assessment, Table 2; (2) Dietary exposure to residues of the active ingredient in food and drinking water is expected to be negligible. PDHP 25279 is a protein and as such is generally expected to be biodegradable through microbial activity in the soil. Supporting this conclusion is the observation that PDHP 25279 is degraded within 5 minutes by subtilisin A, an environmental protease. It is therefore expected that biological processes will reduce run-off and potential exposure of drinking water to negligible levels. The presence of PDHP 25279 on treated crops is likely to be further reduced through normal washing and handling processes. For non-occupational exposure, there is a potential for dermal exposure by handling of plants treated with PDHP 25279. However, PDHP 25279 is expected to be of low toxicity through the dermal route of exposure given the low toxicity through the oral and inhalation routes and dermal studies conducted with the similar harpin protein Ea peptide 91398, which was found to be of low toxicity and not a skin sensitizer.

Based upon the evaluation in the Human Health Risk Assessment, which found no risks of concern from aggregate exposure to PDHP 25279, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of PDHP 25279. In addition, because no threshold effects have been identified for infants and children, EPA determined that an additional Food Quality Protection Act (FQPA) safety factor is not necessary to protect infants and children from anticipated residues of PDHP 25279.

B. Analytical Enforcement Methodology

An analytical method is not needed for PDHP 25279 since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation based on a lack of adverse effects.

C. Response to Comment

One comment was received during the public comment period for the notice of filing. The commentor supported the proposed tolerance exemption and noted the low toxicity, the mode of action, rapid degradation, and low anticipated dietary exposure of PDHP 25279. Based on its review of the data and other information submitted for the proposed tolerance exemption, EPA agrees with the comment in support of the petition to establish a tolerance exemption for residues of PDHP 25279 applied to food commodities.

D. Conclusion

Based on the conclusions detailed in Unit III.A. an exemption from the requirement of a tolerance is established for residues of PDHP 25279 in or on all food commodities when used in accordance with label directions and good agricultural practices.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as

the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, EPA has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*).

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

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 1, 2023.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR part 180 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 § 180.1398 to subpart D to read as follows:

§ 180.1398 Peptide Derived from Harpin Protein (PDHP) 25279; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Peptide Derived from Harpin Protein (PDHP) 25279 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2023–02536 Filed 2–7–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 220216–0049; RTID 0648–XC740]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Non-American Fisheries Act Crab Vessels Operating as Catcher Vessels Using Pot Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by non-American Fisheries Act (AFA) crab vessels that are subject to sideboard limits, and operating as catcher vessels (CVs) using pot gear, in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2023 sideboard limit established for non-AFA crab vessels that are operating as CVs using pot gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), February 5, 2023, through 2400 hours, A.l.t., December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Abby Jahn, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The 2023 Pacific cod sideboard limit established for non-AFA crab vessels, and that are operating as CVs using pot gear in the Central Regulatory Area of the GOA, is 335 metric tons (mt), as established by the final 2022 and 2023 harvest specifications for groundfish in the GOA (87 FR 11599, March 2, 2022), but was incorrectly specified as 316 mt per the 2023 inseason adjustment (87 FR 80088, December 29, 2022). A correction to the 2023 inseason adjustment will be published as soon as possible. However, it is necessary to publish this notification prior to the correction to prevent exceeding the 2023 Pacific cod sideboard limit established for non-AFA crab vessels, and that are operating as CVs using pot gear in the Central Regulatory Area of the GOA.

In accordance with § 680.22(e)(2)(i), the Regional Administrator has determined that the 2023 Pacific cod sideboard limit established for non-AFA crab vessels that are operating as CVs using pot gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 335 mt and is setting aside the remaining 0 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 680.22(e)(3), the Regional Administrator finds that this sideboard directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels using pot gear in the Central Regulatory Area of the GOA.

While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment