this preamble. EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

Therefore, these materials have been approved by EPA for removal from the Alaska SIP, have been removed from incorporation by reference by EPA into that plan, are no longer federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rule of the EPA's approval, and incorporation by reference will be removed by the Director of the Federal Register in the next update to the SIP compilation.[1]

IV. Statutory and Executive Order Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The Alaska SIP does not apply on any Indian reservation land in or in any other area where EPA or Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, this rulemaking does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 18, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time 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 section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: February 10, 2022.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended 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 C—Alaska

§ 52.70 [Amended]

■ 2. In § 52.70, the table in paragraph (c) is amended by removing the entry ''18 AAC 50.240'' under the heading ''18 AAC 50—Article 2. Program Administration''.

[FR Doc. 2022–03303 Filed 2–16–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0840; FRL–9416–01–OCSPP]

[Oxirane, 2-(Phenoxymethyl)-, Polymer With Oxirane, Ether With 2,2′,2″-Nitrilotris[Ethanol] (3:1), Diblock; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock (CAS Reg. No. 2307555–89–9), when used as an inert ingredient in a pesticide chemical formulation. Spring Regulatory Sciences, on behalf of Stepan Company, 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 oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock on food or feed commodities.

[1] 62 FR 27968 (May 22, 1997).

DATES: This regulation is effective February 17, 2022. Objections and requests for hearings must be received on or before April 18, 2022, 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–2021–0840, 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 is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40*.

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0840 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 18, 2022. 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–2021–0840, 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 December 21, 2021 (86 FR 72201) (FRL–8792–06), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN–11646) filed by Spring Regulatory Sciences (6620 Cypresswood Dr., Suite 250, Spring, TX 77379), on behalf of Stepan Company (22 W Frontage Rd., Northfield, IL 60093). The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock (CAS Reg. No. 2307555–89–9). That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request. The Agency did not receive any substantive public comments.

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 use in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of 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 . . .'' and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. To determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to

determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). Oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock (CAS Reg. No. 2307555–89–9) conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize: An adequate biodegradation study (MRID 51712502) was submitted for oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock showing lack of biodegradation (10.6% at 28 days, 13% at 90 days).

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length as listed in 40 CFR 723.250(d)(6).

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

The polymer's number average molecular weight is greater than or equal to 1,000 daltons and less than 10,000 daltons (5483 daltons). Also, the polymer contains less than 2% oligomeric material below MW 500 (2.0%) and less than 5% oligomeric material below MW 1,000 (3.5%).

Thus, Oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock (CAS Reg. No. 2307555–89–9) meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The minimum number average MW of oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock is 5,300 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock conforms to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock to share a common mechanism of toxicity with any other substances, and oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticides/cumulative.*

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold 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 data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock.

VIII. Other Considerations

A. 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.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock.

IX. Conclusion

Accordingly, EPA finds that exempting residues of oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This action establishes 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 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).

XI. 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 8, 2022.

Marietta Echeverria,

Acting Director, Registration Division, 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. In § 180.960, amend Table 1 to § 180.960, by adding in alphabetical order the polymer ''Oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock, minimum number average molecular weight (in amu), 5,300'' to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO § 180.960

Polymer	CAS No.
* * * * * * *	
Oxirane, 2-(phenoxymethyl)-, polymer with oxirane, ether with 2,2′,2″-nitrilotris[ethanol] (3:1), diblock, minimum number average molecular weight (in amu), 5,300	2307555–89–9
* * * * * * *	

[FR Doc. 2022–03456 Filed 2–16–22; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 5b

[Docket Number NIH–2016–0002]

RIN 0925–AA62

Privacy Act; Implementation

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or Department) is issuing this final rule to make effective the exemptions that were previously proposed for a subset of records covered in a new Privacy Act system of records, No. 09–25–0165, NIH Loan Repayment Records, which is maintained by the National Institutes of Health (NIH). The system of records covers records used to manage and evaluate the Loan Repayment Programs (LRPs) at NIH. The exemptions are necessary to maintain the integrity of the NIH peer review and award processes by enabling NIH to protect the identities of reviewers.

DATES: This final rule is effective February 17, 2022.

FOR FURTHER INFORMATION CONTACT: Dustin Close, Office of Management Assessment, National Institutes of Health, 6705 Rockledge Drive, Suite 601, Bethesda, Maryland 20892, telephone 301–402–6469, email *privacy@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The NIH Loan Repayment Programs (LRPs) are administered by the Division of Loan Repayment (DLR) within NIH's Office of Extramural Research. DLR provides repayment of student loans for approved applicants to encourage outstanding health professionals to pursue careers in biomedical, behavioral, social, and clinical research. Research health professionals who owe qualified educational debt and who meet eligibility criteria may apply for student loan repayment. A peer review process recommends applicants for loan repayments. The peer review process is committee-based, with a peer review group comprised of individual reviewers, referees, or other recommenders (hereafter collectively referred to as Reviewers). Reviewers are primarily non-government experts qualified by training and experience in scientific or technical fields, or as authorities knowledgeable in disciplines and fields related to the areas under review. Reviewers give DLR expert recommendations and materials (such as ratings, summaries, and communications) about applicants' suitability, eligibility, or qualifications for student loan repayments under express promises that the Reviewers will not be identified as the sources of the information. DLR uses the information solely for the purpose of determining applicants' suitability, eligibility, or qualifications for Federal loan repayment. System of records 09–25–0165 covers records about health professionals who apply for student loan repayments and about other categories of individuals who are related to the applications. These records include material that could reveal the identity of the Reviewers either directly or indirectly.

Under the Privacy Act of 1974, as amended (Privacy Act, 5 U.S.C. 552a, or ''Privacy Act''), individuals have a right of access to records about themselves in Federal agency systems of records, and other rights with respect to those records (such as notification, amendment, and an accounting of disclosures), but the Act permits certain types of systems of records (identified in section 552a(j) and (k)) to be exempted from certain requirements of the Act. Subsection (k)(5) permits the head of an agency to promulgate rules to exempt from the requirements in subsections (c)(3) and (d)(1) through (4) of the Act investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal contracts, to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Federal Government under an express promise that the identity of the source would be held in confidence.

In accordance with the Privacy Act, HHS/NIH proposed to exempt material that would identify a confidential source in system of records 09–25–0165 from the notification, access, and amendment requirements of the Act pursuant to subsection (k)(5) of the Act, as described in a notice of proposed rulemaking (NPRM) published in the **Federal Register** (86 FR 2633) for public comment on January 13, 2021. The agency also published a modified notice describing system of records 09–25–0165 (SORN) in the **Federal Register** (86 FR 2677) for public comment the same day. The 60-day public comment period provided for both the SORN and the NRPM expired March 15, 2021. Thirteen comments were received on the NPRM and no comments were received on the SORN. The comments received applauded NIH's efforts to exempt material that would identify Reviewers contained within the system of records as specified in the notice. Additionally, none of the commentors recommended any changes to the proposed exemptions or the SORN. Therefore, HHS/NIH has made no changes to the proposed exemptions in the NPRM or to the SORN.

NIH believes the exemptions are necessary to maintain the integrity of the NIH peer review and award processes. Protecting Reviewer identities as the sources of the information they provide protects them from harassment, intimidation, and other attempts to improperly influence award outcomes, and ensures that they are not reluctant to provide sensitive information or frank assessments. Case law has held that exemptions promulgated under subsection (k)(5) may protect source-identifying material even where the identity of the source is known. Therefore, NIH solicits Reviewers to assess applicants for loan repayment programs under an express promise of confidentiality.

The specific rationales that support the exemptions concerning each affected Privacy Act provision, are as follows:

- Subsection (c)(3). An exemption from the requirement to provide an accounting of disclosures to record subjects is needed to protect the identity of any Reviewer who is expressly promised confidentiality. Providing an accounting of disclosures to an applicant could identify specific Reviewers as sources of recommendations or evaluative input received, or to be received, on the application. Inappropriately revealing the Reviewers' identities in association with the nature and scope of their assessments or evaluations could lead them to alter or destroy their assessments or evaluations or subject them to harassment, intimidation, or other improper influence, which would impede or compromise the fairness and objectivity of the loan repayment application review process; constitute an unwarranted invasion of the personal privacy of the Reviewer; and violate the express promise of confidentiality made to the Reviewer.
- Subsection (d)(1). An exemption from the access requirement is needed both during and after an application review proceeding to avoid inappropriately revealing the identity of the Reviewers. Protecting the Reviewers' identities from access by record subjects is necessary to maintain the integrity of the review process. It ensures Reviewers provide candid assessments or