

# Proposed Rules

Federal Register

Vol. 85, No. 221

Monday, November 16, 2020

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 21 CFR Part 6

### 42 CFR Part 1, 404

### 45 CFR Part 6

[Docket No. HHS-OS-2020-0012]

RIN 0991-AC24

### Securing Updated and Necessary Statutory Evaluations Timely

**AGENCY:** Department of Health and Human Services (HHS).

**ACTION:** Proposed rule; public hearing.

**SUMMARY:** This document announces a public hearing to receive information and views on the Notice of Proposed Rulemaking (NPRM) entitled "Securing Updated and Necessary Statutory Evaluations Timely."

**DATES:** November 23, 2020, 10 a.m.–2 p.m. Eastern Time (ET). The ending time of this public hearing may change based on public interest. The most up-to-date information about the public hearing will be available on the HHS.gov website at <https://www.hhs.gov/regulations/comment-on-open-rules/index.html>.

**ADDRESSES:** This meeting will be held virtually by WebEx and teleconference.

The public can join the meeting by: (Audio Portion) Calling the conference phone number +1-415-527-5035 and providing the following information:

Meeting Number (access code): 199 934 0311

Meeting Password: jB4kisMjt47

### FOR FURTHER INFORMATION CONTACT:

James Lawrence, 200 Independence Avenue, SW Room 713F, Washington, DC 20201; or by email at [reviewnprm@hhs.gov](mailto:reviewnprm@hhs.gov); or by telephone at 1-877-696-6775.

**SUPPLEMENTARY INFORMATION:** To further comply with the Regulatory Flexibility Act and certain Executive Orders, as well as to ensure its regulations have

appropriate impacts, the U.S. Department of Health and Human Services (HHS) issued a notice of proposed rulemaking (NPRM) to set expiration dates for its regulations (subject to certain exceptions), unless the Department periodically assesses the regulations to determine if they are subject to the RFA, and if they are, performs a review that satisfies the criteria in the RFA.

The NPRM was published in the **Federal Register** on November 4, 2020. See 85 FR 70096, <https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-23888.pdf>. The public comment period closes on December 4, 2020, except that portions of the proposed rule amending 42 CFR parts 400–429 and parts 475–499 are due January 4, 2021.

The public hearing will be held during the public comment period. This hearing is to provide an open forum for the presentation of information and views concerning all aspects of the NPRM by interested persons.

In preparing a final regulation, the Secretary will consider the administrative record of this hearing along with all other written comments received during the comment period specified in the NPRM. Individuals or representatives of interested organizations are invited to participate in the public hearing in accordance with the schedule and procedures set forth below. Persons who wish to participate are requested to file a notice of participation with HHS on or before November 19, 2020. The notice should be emailed to [reviewnprm@hhs.gov](mailto:reviewnprm@hhs.gov) or mailed to James Lawrence, 200 Independence Avenue SW, Room 713F, Washington, DC 20201. To ensure timely handling, any outer envelope or the subject line of an email should be clearly marked "Review NPRM Hearing." The notice of participation should contain the interested person's name, address, email address, telephone number, any business or organizational affiliation of the person desiring to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation. Groups that have similar interests should consolidate their comments as part of one presentation. Time available for the hearing will be allocated among the persons who properly file notices of participation. If time permits, interested

parties attending the hearing who did not submit notices of participation in advance will be allowed to make an oral presentation at the conclusion of the hearing.

Persons who find that there is insufficient time to submit the required information in writing may give oral notice of participation by calling James Lawrence at 1-877-696-6775, no later than November 20, 2020.

After reviewing the notices of participation and accompanying information, HHS will schedule each appearance and notify each participant by mail, email, or telephone of the time allotted to the person(s) and the approximate time the person's oral presentation is scheduled to begin.

A summary of comments and a recording of the hearing will be made available for public inspection on the HHS.gov website, <https://www.hhs.gov/>, as soon as they have been prepared.

Dated: November 10, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020-25246 Filed 11-12-20; 11:15 am]

BILLING CODE 4150-26-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[EPA-HQ-OPPT-2020-0513; FRL-10016-39]

RIN 2070-AB27

### Significant New Use Rules on Certain Chemical Substances (21-1.B)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances which are the subject of premanufacture notices (PMNs). This action would require persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use by this proposed rule. This action would further require that persons not

commence manufacture or processing for the significant new use until they have submitted a Significant New Use Notice (SNUN), and EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken any risk management actions as are required as a result of that determination.

**DATES:** Comments must be received on or before December 16, 2020.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0513, using the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health emergency, 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:** For technical information contact: William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4163; email address: [wysong.william@epa.gov](mailto:wysong.william@epa.gov).

For general information contact: The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

###### *A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. 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:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import

certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions. This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA, which would include the SNUR requirements should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after December 16, 2020 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

###### *B. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit CBI to EPA through [regulations.gov](https://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

##### **II. Background**

###### *A. What action is the Agency taking?*

EPA is proposing these SNURs under TSCA section 5(a)(2) for chemical substances which are the subjects of PMNs P–18–175 and P–19–38. These proposed SNURs would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

The record for these proposed SNURs, identified as docket ID number EPA–HQ–OPPT–2020–0513, includes information considered by the Agency in developing these proposed SNURs.

###### *B. What is the Agency's authority for taking this action?*

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four TSCA section 5(a)(2) factors listed in Unit III.

###### *C. Do the SNUR general provisions apply?*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the chemical substance is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

##### **III. Significant New Use Determination**

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit. During its review of these chemicals, EPA identified certain conditions of use that are not intended by the submitters, but reasonably foreseen to occur. EPA is proposing to designate those reasonably foreseen conditions of use as well as certain other circumstances of use as significant new uses.

#### IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements be added to 40 CFR part 721, subpart E for the chemical substances identified in this unit. For each chemical substance, EPA provides the following information in this unit:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR.
- Potentially useful information.
- CFR citation assigned in the regulatory text section of these proposed rules. The regulatory text section of these proposed rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the proposed rules, may be claimed as CBI.

The chemical substances that are the subject of these proposed SNURs are undergoing premanufacture review. In addition to those conditions of use intended by the submitter, EPA has identified certain other reasonably foreseen conditions of use. EPA has preliminarily determined that the chemicals under their intended conditions of use are not likely to present an unreasonable risk. However, EPA has not assessed risks associated with the reasonably foreseen conditions of use for these chemicals. EPA is proposing to designate these reasonably foreseen conditions of use and other circumstances of use as significant new uses. As a result, those significant new uses cannot occur without first going

through a separate, subsequent EPA review and determination process associated with a SNUN.

The substances subject to these proposed rules are as follows:

PMN Number: P-18-175.

*Chemical name:* Formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol and phenol, Bu ether.

*CAS number:* 2215936-67-5.

*Basis for action:* The PMN states that the use of the substance will be as a can coating for food and non-food contact. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for aquatic toxicity, serious eye damage, skin irritation, and specific target organ toxicity if the chemical is not used following the limitations noted. This proposed SNUR designates the following as “significant new uses” requiring further review by EPA:

- Release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

*Potentially useful information:* EPA has determined that certain information about the environmental and health effects of the PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of aquatic toxicity, eye irritation/corrosion, skin irritation/corrosion, and specific target organ toxicity testing would help characterize the potential environmental and health effects of the PMN substance.

*CFR citation:* 40 CFR 721.11566.

PMN Number: P-19-38.

*Chemical name:* Fatty acids, coco, iso-Bu esters.

*CAS number:* 91697-43-7.

*Basis for action:* The PMN states that the use of the substance will be as an ink carrier for the ceramic industries. Based on the physical/chemical properties of the PMN substance and SAR analysis of test data on analogous substances, EPA has identified concerns for aquatic toxicity if the chemical is not used following the limitations noted. This proposed SNUR designates the following as “significant new uses” requiring further review by EPA:

- Release of the PMN substance resulting in surface water concentrations that exceed 1 ppb.

*Potentially useful information:* EPA has determined that certain information about the environmental effects of the

PMN substance may be potentially useful if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of aquatic toxicity testing would help characterize the potential environmental effects of the PMN substance.

*CFR citation:* 40 CFR 721.11567.

#### V. Rationale and Objectives of the Proposed Rule

##### A. Rationale

During review of the PMNs submitted for the chemical substances that are the subject of these proposed SNURs and as further discussed in Unit IV., EPA identified certain other reasonably foreseen conditions of use, in addition to those conditions of use intended by the submitter. EPA has preliminarily determined that the chemical under the intended conditions of use is not likely to present an unreasonable risk. However, EPA has not assessed risks associated with the reasonably foreseen conditions of use. EPA is proposing to designate these conditions of use as well as certain other circumstances of use as significant new uses. As a result, those significant new uses cannot occur without going through a separate, subsequent EPA review and determination process associated with a SNUN.

##### B. Objectives

EPA is proposing these SNURs because the Agency wants:

- To have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that the chemical, under the conditions of use, is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.
- To be able to complete its review and determination on each of the PMN substances, while deferring analysis on

the significant new uses proposed in these rules unless and until the Agency receives a SNUN.

Issuance of a proposed SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at <https://www.epa.gov/tscainventory>.

#### VI. Applicability of the Proposed Rules to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule were undergoing premanufacture review at the time of signature of this proposed rule and were not on the TSCA Inventory. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for the chemical substances subject to these proposed SNURs, EPA concludes that the proposed significant new uses are not ongoing.

EPA designates November 5, 2020 (date of web posting of this proposed rule) as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified on or after that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under section 5 allowing manufacture or processing to proceed. In developing this proposed rule, EPA has recognized that, given EPA's general practice of posting proposed rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before **Federal Register** publication of the proposed rule.

#### VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: If a

person is required to submit information for a chemical substance pursuant to a rule, order or consent agreement under TSCA section 4 (15 U.S.C. 2603), then TSCA section 5(b)(1)(A) (15 U.S.C. 2604(b)(1)(A)) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information for all SNURs listed here. Descriptions are provided for informational purposes. The potentially useful information identified in Unit IV. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance, which may assist with EPA's analysis of the SNUN.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

The potentially useful information described in Unit IV. may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests. SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

#### VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

#### IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket for this rulemaking.

#### X. 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 and Executive Order 13563: Improving Regulations and Regulatory Review*

This action proposes to establish SNURs for new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

#### *B. Paperwork Reduction Act (PRA)*

According to the PRA, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden

requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

### C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this proposed SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a “significant new use.” Because these uses are “new,” based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 12 in FY2016, 13 in FY2017, and 11 in FY2018, only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to

be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

### D. Unfunded Mandates Reform Act (UMRA)

Based on EPA’s experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this proposed rule. As such, EPA has determined that this proposed rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1531–1538 *et seq.*).

### E. Executive Order 13132: Federalism

This action will not have federalism implications because it is not expected to have a substantial direct effect on 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

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

This action will not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000).

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

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

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

### I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

### J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

### List of Subjects in 40 CFR Part 721 Environmental Protection, Chemicals, Hazardous Substances, Reporting and Recordkeeping Requirements.

Dated: October 30, 2020.

**Tala Henry,**

*Deputy Director, Office of Pollution Prevention and Toxics.*

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR part 721 as follows:

### PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

■ 1. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add §§ 721.11566 and 721.11567 to subpart E to read as follows:

#### Subpart E—Significant New Uses for Specific Chemical Substances

\* \* \* \* \*

#### § 721.11566 Formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol and phenol, Bu ether.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol and phenol, Bu ether (PMN P–18–175, CAS No. 2215936–67–5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 1.

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

#### **§ 721.11567 Fatty acids, coco, iso-Bu esters.**

(a) *Chemical substance and significant new uses subject to reporting*.

(1) The chemical substance identified as fatty acids, coco, iso-Bu esters (PMN P-19-38, CAS No. 91697-43-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 1.

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

[FR Doc. 2020-25049 Filed 11-13-20; 8:45 am]

BILLING CODE 6560-50-P

## **DEPARTMENT OF THE INTERIOR**

### **Fish and Wildlife Service**

#### **50 CFR Part 17**

[Docket No. FWS-R4-ES-2019-0018; FF09E22000 FXES113090FEDR 212]

RIN 1018-BE09

#### **Endangered and Threatened Wildlife and Plants; Reclassification of the Red-Cockaded Woodpecker From Endangered to Threatened With a Section 4(d) Rule**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule; announcement of a public informational meeting and public hearing.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), recently proposed to reclassify the endangered red-cockaded woodpecker (*Dryobates borealis*) as a threatened species with a rule issued under section 4(d) of the Endangered Species Act of 1973 (Act), as amended. We announced a 60-day public comment period on the proposed rule, ending December 7, 2020. We now announce a public informational meeting and public hearing on the proposed rule.

#### **DATES:**

*Public informational meeting and public hearing:* On December 1, 2020, we will hold a public informational meeting from 6 to 7:30 p.m., Eastern Time, followed by a public hearing from 7:30 to 9 p.m., Eastern Time.

*Comment submission:* We will accept written comments received or postmarked on or before December 7, 2020. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date.

**ADDRESSES:** *Availability of documents:* You may obtain copies of the October 8, 2020, proposed rule and associated documents on the internet at <http://www.regulations.gov> under Docket No. FWS-R4-ES-2019-0018.

*Public informational meeting and public hearing:* The public informational meeting and the public hearing will be held virtually using the Zoom platform. See Public Hearing, below, for more information.

*Comment submission:* You may submit written comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <http://www.regulations.gov>. In the Search box, enter FWS-R4-ES-2019-0018, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on “Comment Now!”

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS-R4-ES-2019-0018, U.S. Fish and Wildlife Service, MS: JAO/3W, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

We request that you send comments only by the methods described above. We will post all comments on <http://www.regulations.gov>. This generally

means that we will post any personal information you provide us (see Public Comments, below, for more information).

#### **FOR FURTHER INFORMATION CONTACT:**

Aaron Valenta, Chief, Division of Restoration and Recovery, U.S. Fish and Wildlife Service, Southeast Regional Office, 1875 Century Boulevard, Atlanta, GA 30345; telephone 404-679-4144. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800-877-8339.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

On October 8, 2020, we published a proposed rule (85 FR 63474) to reclassify the red-cockaded woodpecker from endangered to threatened (*i.e.*, “downlist” the species) under the Act (16 U.S.C. 1531 *et seq.*). The proposed rule established a 60-day public comment period, ending December 7, 2020. We received a request for a public hearing. Therefore, we are announcing a public informational meeting and a public hearing to allow the public an additional opportunity to provide comments on the proposed rule.

For a description of previous Federal actions concerning the red-cockaded woodpecker and information on the types of comments that would be helpful to us in promulgating this rulemaking action, please refer to the October 8, 2020, proposed rule (85 FR 63474).

##### **Public Hearing**

We have scheduled a public informational meeting and public hearing on our October 8, 2020, proposed rule to reclassify the red-cockaded woodpecker (85 FR 63474). We will hold the public informational meeting and public hearing on the date and at the times listed above under *Public informational meeting and public hearing* in **DATES**. We are holding the public informational meeting and public hearing via the Zoom online video platform and via teleconference so that participants can attend remotely. For security purposes, registration is required. To listen and view the meeting and hearing via Zoom, listen to the meeting and hearing by telephone, or provide oral public comments at the public hearing by Zoom or telephone, you must register. For information on how to register, or if you encounter problems joining Zoom the day of the meeting, visit <https://www.fws.gov/southeast/wildlife/birds/red-cockaded-woodpecker/#recovery-plan-section>. Registrants will receive the Zoom link