

intermittently enforced over the course of approximately 24 days. It is categorically excluded from further review under paragraph L[60a] of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

#### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

#### List of Subjects in 33 CFR Part 165

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

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

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

**Authority:** 46 U.S.C. 70034, 70051; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T05-0285 to read as follows:

#### § 165.T05-0285 Security Zone; Christina River, Newport, DE.

(a) *Location.* The following area is a security zone: All waters of the Christina River, from shoreline to shoreline bounded on the east by a line drawn from 39°42.55' North Latitude (N), 075°35.88' West Longitude (W), thence southerly to 39°42.50' N, 075°35.87' W thence along the Christina River in a westerly direction and bounded by the South James Street Bridge at 39°42.63' N, 075°36.53' W. These coordinates are based on North American Datum 83 (NAD83).

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

*Designated representative* means any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port Delaware Bay (COTP) to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via

VHF-FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of the regulations in this section.

*Official patrol vessel* means any Coast Guard, Coast Guard Auxiliary, State, or local law enforcement vessel assigned or approved by the COTP.

*USSS protectee* means any person for whom the United States Secret Service (USSS) requests implementation of a security zone in order to supplement protection of said person(s).

(c) *Regulations.* (1) In accordance with the general regulations contained in § 165.33, entry into or movement within this zone is prohibited unless authorized by the COTP, Sector Delaware Bay, or designated representative.

(2) Only vessels or people specifically authorized by the Captain of the Port, Delaware Bay, or designated representative, may enter or remain in the regulated area. To request permission to enter or remain in the regulated area contact the COTP or the COTP's representative on VHF-FM channel 13 or 16. Vessel operators and persons within the security zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. No person may swim upon or below the surface of the water of this security zone unless authorized by the COTP or his designated representative.

(3) Upon being hailed by an official patrol vessel or the designated representative, by siren, radio, flashing light, or other means, the operator of the vessel shall proceed as directed. Failure to comply with lawful direction may result in expulsion from the regulated area, citation for failure to comply, or both.

(d) *Enforcement.* (1) This security zone is effective without actual notice from April 30, 2021 through May 17, 2021. For the purposes of enforcement, actual notice will be used from 2 p.m. on April 23, 2021 until April 30, 2021.

(2) This security zone will be enforced with actual notice by the U.S. Coast Guard representatives on scene, as well as other methods listed in § 165.7. The Coast Guard will enforce the security zone created by this section only when it is necessary for the protection of persons under the protection of the USSS traveling across the route 141 bridge in Newport, Delaware. The U.S. Coast Guard may be additionally assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

Dated: April 23, 2021.

**Leon McClain, Jr.,**

*Captain, U.S. Coast Guard, Acting Captain of the Port, Delaware Bay.*

[FR Doc. 2021-08853 Filed 4-29-21; 8:45 am]

**BILLING CODE 9110-04-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 9, 721, and 725

[EPA-HQ-OPPT-2020-0094; FRL-10016-30]

RIN 2070-AB27

### Significant New Use Rules on Certain Chemical Substances (20-3.B)

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

**ACTION:** Final rule.

**SUMMARY:** EPA is issuing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances which were the subject of premanufacture notices (PMNs) and a microorganism that was the subject of a Microbial Commercial Activity Notice (MCAN). This action requires 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 rule. This action further requires 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:** This rule is effective on June 29, 2021. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on May 14, 2021.

#### 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 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. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20 or 725.920 for the MCAN substance, any persons who export or intend to export a chemical substance that is the subject of this rule 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. How can I access the docket?

The docket includes information considered by the Agency in developing the proposed and final rules. The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0094, is available at <https://www.regulations.gov> and at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. 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 OPPT Docket is (202) 566-0280.

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>.

## II. Background

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

EPA is finalizing SNURs under TSCA section 5(a)(2) for chemical substances which were the subject of MCAN J-19-1 and PMNs P-18-391 and P-20-13. These SNURs 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.

### 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, and (for microorganisms) 40 CFR part 725, subpart L. 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 significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before manufacture or processing for the significant new use can commence. If EPA determines that the significant new use 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

### A. Determination Factors

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 designating those reasonably foreseen conditions of use as well as certain other circumstances of use as significant new uses.

### B. Procedures for Significant New Uses Claimed as Confidential Business Information (CBI)

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1) and has referenced it to apply to other SNURs.

Under these procedures a manufacturer or processor may request EPA to determine whether a specific use would be a significant new use under the rule. The manufacturer or processor

must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in 40 CFR 721.1725(b)(1) with that under 40 CFR 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, *i.e.*, the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

#### IV. Public Comments

EPA received public comments on the proposed rule (85 FR 15406, March 18, 2020) from four identifying entities. The Agency's responses are presented in the Response to Public Comments document that is available in the docket for this rule. EPA has made changes to the final rule as described in these comments.

#### V. Substances Subject to This Rule

EPA is establishing significant new use and recordkeeping requirements for chemical substances in 40 CFR part 721, subpart E, and in 40 CFR part 725 for one chemical substance that is a microorganism (MCAN J-19-1). In Unit IV. of the proposed SNUR, EPA provided the following information for each chemical substance:

- PMN or MCAN 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 this final rule.

The regulatory text section of these rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the rules, may be claimed as CBI.

#### VI. Rationale and Objectives of the Rule

##### A. Rationale

During review of the PMNs and MCAN submitted for the chemical substances that are the subject of these SNURs and as further discussed in Unit IV. of the proposed rule, 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 designating 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 issuing 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 section 5(a)(3)(C) that the significant new 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 or MCAN substances, while deferring analysis on the significant new uses

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

Issuance of a 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/tsca-inventory>.

#### VII. Applicability of the 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 rule were undergoing premanufacture review at the time of signature of the 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 SNURs EPA concluded at the time of signature of the proposed rule that the designated significant new uses were not ongoing.

EPA designated March 4, 2020 (the date of web posting of the 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 began commercial manufacture or processing of the chemical substances for a significant new use identified on or after that date will 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.

#### VIII. 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, then TSCA section 5(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. of the proposed rule lists potentially useful information for all SNURs listed here. Descriptions are provided for informational purposes. The potentially useful information identified in Unit IV. of the proposed rule 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 election. 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. of the proposed rule 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.

#### IX. 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 (or 40 CFR 725.25 and 725.27 for an MCAN). E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

#### X. Economic Analysis

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

#### XI. 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 establishes 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 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. 0574). 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 RFA section 605(b), 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this 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 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 action. As such, EPA has determined that this action 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. 1501 *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. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

*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 action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), 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).

*K. Congressional Review Act (CRA)*

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report containing this rule and other required information to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects**

*40 CFR Part 9*

Environmental protection, Reporting and recordkeeping requirements.

*40 CFR Part 721*

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

*40 CFR Part 725*

Environmental protection, Chemicals, Hazardous substances, Microorganisms, Reporting and recordkeeping requirements.

Dated: January 14, 2021.

**Tala Henry,**

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

**Editorial Note:** This document was received for publication by the Office of the Federal Register on April 23, 2021.

Therefore, for the reasons set forth in the preamble, EPA amends 40 CFR parts 9, 721, and 725 as follows:

**PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT**

■ 1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241,

242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1, amend the table by adding entries for §§ 721.11460 and 721.11461 in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

* * * * *				
40 CFR citation		OMB control No.		
*	*	*	*	*
Significant New Uses of Chemical Substances				
* * * * *				
721.11460	.....			2070–0012
721.11461	.....			2070–0012
*	*	*	*	*
* * * * *				

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

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

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

■ 4. Add §§ 721.11460 and 721.11461 to read as follows:

**§ 721.11460 1-Propanaminium, N-(carboxymethyl)-N,N-dimethyl-3-[(3,5,5-trimethyl-1-oxohexyl)amino]-, inner salt.**

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

(1) The chemical substance identified as 1-Propanaminium, N-(carboxymethyl)-N,N-dimethyl-3-[(3,5,5-trimethyl-1-oxohexyl)amino]-, inner salt. (PMN P–18–391; CASRN 2169783–63–3) 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) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance for any use that results in inhalation exposures.

(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 (i) 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.

**§ 721.11461 2-Propenoic acid, 2-methyl-, (2-oxo-1,3-dioxolan-4-yl)methyl ester.**

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

(1) The chemical substance identified as 2-propenoic acid, 2-methyl-, (2-oxo-1,3-dioxolan-4-yl)methyl ester (PMN P-20-13; CASRN 13818-44-5) 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) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (o). It is a significant new use to manufacture or import greater than the confidential annual production volume identified in the PMN.

(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 (i) 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.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

**PART 725—REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS**

■ 5. The authority citation for part 725 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, 2613, and 2625.

■ 6. Add § 725.1080 to read as follows:

**§ 725.1080 *Trichoderma reesei* (generic).**

(a) *Microorganism and significant new uses subject to reporting.* (1) The genetically modified microorganism identified as *Trichoderma reesei* strain 3CH-3 (MCAN J-19-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2)(i) The significant new use is any manufacturing, processing, or use of the microorganism other than in a fermentation system that meets all of the following conditions:

(A) Enzyme production occurs by submerged fermentation (*i.e.*, for enzyme production, growth of the microorganism occurs beneath the surface of the liquid growth medium); and

(B) Any further fermentation, such as saccharification (*i.e.*, addition of *Trichoderma reesei* fermentation broth to solid plant material or insoluble substrate after the standard industrial fermentation is completed), is initiated only after the inactivation of the microorganism as delineated in § 725.422(d).

(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 (i) of this chapter, are applicable to manufacturers and processors of this substance.

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

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 62**

[EPA-R06-OAR-2021-0059; FRL-10022-53-Region 6]

**Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; Louisiana; Control of Emissions From Existing Other Solid Waste Incineration Units**

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

**ACTION:** Final rule.

**SUMMARY:** Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is notifying the public that we have received a CAA section 111(d)/129 negative declaration from Louisiana for existing incinerators subject to the Other Solid Waste Incineration units (OSWI) emission guidelines (EG). This negative declaration from Louisiana certifies that incinerators subject to the OSWI EG and the requirements of sections 111(d) and 129 of the CAA do not exist within the jurisdiction of Louisiana. The EPA is accepting the negative declaration and amending the agency regulations in accordance with the requirements of the CAA.

**DATES:** This rule is effective on June 1, 2021.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-R06-OAR-2021-0059. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Karolina Ruan Lei, EPA Region 6 Office, Air and Radiation Division—State Planning and Implementation Branch, 1201 Elm Street, Suite 500, Dallas, TX 75270, (214) 665-7346, [ruan-lei.karolina@epa.gov](mailto:ruan-lei.karolina@epa.gov). Out of an abundance of caution for members of the public and our staff, the EPA Region 6 office will be closed to the public to reduce the risk of transmitting COVID-19. Please call or email the contact listed above if you need alternative access to material indexed but not provided in the docket.

**SUPPLEMENTARY INFORMATION:** Throughout this document “we,” “us,” and “our” means the EPA.

**I. Background**

The background for this action is discussed in detail in our February 24, 2021, proposal (86 FR 11212). In that document we proposed to accept the OSWI negative declaration from the Louisiana Department of Environmental Quality (LDEQ) and to amend the Code of Federal Regulations (CFR) in accordance with the requirements of the CAA. No comments were received on the February 24, 2021, proposal.

**II. Final Action**

In this final action, the EPA is amending 40 CFR part 62, subpart T, to reflect receipt of the negative declaration letter from LDEQ, received on November 24, 2020, certifying that there are no existing incinerators subject to 40 CFR part 60, subpart FFFF, in its jurisdiction in accordance with 40 CFR 60.23(b), 40 CFR 62.06, 40 CFR 60.2982, and sections 111(d) and 129 of the CAA.

**III. Statutory and Executive Order Reviews**

Under the CAA, the Administrator is required to approve a CAA section 111(d)/129 submission that complies