(1) Data (where necessary, data would be made available subject to access and use restrictions);

(2) Associated protocols necessary to understand, assess, and extend conclusions;

(3) Computer codes and models involved in the creation and analysis of such information;

(4) Recorded factual materials; and

(5) Detailed descriptions of how to access and use such information.

(b) The provisions of this section apply to data and models underlying pivotal regulatory science or pivotal science regardless of who funded or conducted the underlying data, models, or other regulatory science or pivotal science. The agency shall make reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data and models available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data and models are controlled by third parties, EPA may work with those parties to endeavor to make the data and models available in a manner that complies with this section.

■ 6. Revise § 30.6 to read as follows:

§ 30.6 What additional requirements pertain to the use of data and models underlying pivotal science or pivotal regulatory science?

EPA shall describe and document any assumptions and methods used and shall describe variability and uncertainty. EPA shall evaluate the appropriateness of using default assumptions on a case-by-case basis. EPA shall clearly explain the scientific basis for critical assumptions used in the analysis that drove the analytical results and subsequent decisions and shall present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies, including but not limited to those that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

■ 7. Revise § 30.7 to read as follows:

§ 30.7 What role does independent peer review have in this section?

EPA shall conduct independent peer review on all pivotal regulatory science used to justify significant regulatory decisions and on all pivotal science underlying influential scientific information, consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review and the exemptions described therein. Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results.

■ 8. Revise § 30.9 to read as follows:

§ 30.9 May the EPA Administrator grant exemptions to this part?

The Administrator may grant an exemption to this part on a case-by case basis if he or she determines that compliance is impracticable because technological barriers render sharing of the data or models infeasible, the development of the data or model was completed or updated before [*EFFECTIVE DATE OF FINAL RULE*] or making the data and models publicly available would conflict with laws governing privacy, confidentiality, confidential business information, or national and homeland security.

[FR Doc. 2020–05012 Filed 3–17–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 721 and 725

[EPA–HQ–OPPT–2020–0094; FRL–10005–76]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (20–3.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) and a microorganism that was the subject of a Microbial Commercial Activity Notice (MCAN). 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, and EPA has conducted a review of the notice, made an appropriate determination on the notice under TSCA, and has taken any risk management actions as are required as a result of that determination.

DATES: Comments must be received on or before April 17, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0094, by one of the following methods:

- *Federal eRulemaking Portal: http://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.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 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 *http://www.epa.gov/dockets/contacts.html.*

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

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@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.*

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 certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these proposed SNURs would need to certify their compliance with 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 or 725.920 for the MCAN substance, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after April 17, 2020 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) 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 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 *http://www.epa.gov/dockets/comments.html.*

II. Background

A. What action is the Agency taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for chemical substances which were the subjects of MCAN J–19–1 and PMNs P–18–391 and P–20–13. 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 the proposed SNURs on these chemicals was established as docket ID number EPA–HQ–OPPT–2020–0094. That record 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. In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence.

C. Applicability of General Provisions

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 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 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

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 conditions of use of 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 significant new uses.

IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for two chemical substances in 40 CFR part 721, subpart E and one chemical substance that is a microorganism in MCAN J–19–1 in 40 CFR part 725. In this unit, EPA provides the following information for each chemical substance:

• PMN or 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. This is information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a

SNUN for a significant new use designated by the SNUR.

• 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 and other potential conditions of use as significant new uses. As a result, those conditions of use are no longer reasonably foreseen to 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–18–391

Chemical name: 1-Propanaminium, N-(carboxymethyl)-N, N-dimethyl-3-[(3,5, 5-trimethyl-1-oxohexyl), amino]-inner salt.

CAS number: 2169783–63–3.

Basis for action: The PMN states that the use of the substance will be in liquid laundry detergent. Based on the physical/chemical properties of the PMN substance, test data on the PMN substance and SAR analysis of test data on analogous substances, EPA has identified concerns for lung effects (lung surfactancy), systemic (maternal) and developmental effects, and irritation to skin and eyes if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

• It is a significant new use to manufacture, process, or use the substance for any use that results in inhalation exposures.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance 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 specific target organ toxicity would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721. 11460.

PMN Number: P–20–13

Chemical name: 2-Propenoic acid, 2-methyl-, (2-oxo-1,3-dioxolan-4-yl)methyl ester.

CAS number: 13818–44–5.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be in UV curable inks. Based on the physical/chemical properties of the PMN substance and SAR analysis of test data on analogous substances, EPA has identified concerns for respiratory sensitization, eye irritation, systemic toxicity, neurotoxicity, reproductive and developmental toxicity, immunotoxicity, liver and kidney effects if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

• Annual manufacture (including import) volume greater than the confidential amount identified in the PMN;

• Use other than the confidential use described in the PMN; and

• Use in a consumer product.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance 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 respiratory sensitization, specific target organ toxicity, neurotoxicity, and reproductive toxicity (developmental effects) testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721. 11461.

MCAN Number: J–19–1

Chemical name: Trichoderma reesei strain 3CH–3.

CAS number: Not available.

Basis for action: The MCAN states that the use of the substance will be to induce the production of biomass-degrading cellulases used for the manufacture of sugars or sugar-derived substances. EPA determined that certain fermentation conditions, other than the typical submerged standard industrial fermentation process for enzyme production, could result in increased exposures. Specifically, EPA is concerned that where growth on plant material or on solid substrates occurs, *T. reesei* has been shown to produce a secondary metabolite known as paracelsin, which is associated with a variety of toxic effects to mammalian and bacterial cells. The intended conditions of use of the MCAN microorganism described in the MCAN include the following protective measures:

• No manufacture, 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);

(B) Any fermentation of solid plant material or insoluble substrate, to which *Trichoderma reesei* fermentation broth is added after the standard industrial fermentation is completed, is initiated only after the inactivation of the microorganism as delineated in 40 CFR 725.422(d).

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that the results of the following studies would help characterize any potential human health and environmental effects of the MCAN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR:

• Investigation of whether paracelsin will be produced, and at what levels if the genetically-modified *T. reesei* is grown on various plant biomass materials for different durations under various fermentation conditions in cellulosic biomass facilities.

• If paracelsin is produced, a study of whether paracelsin would be denatured/inactivated during production and processing.

• If paracelsin is released from the facility, a study of whether paracelsin would be degraded/inactivated during wastewater treatment.

• If released to the environment, studies on the persistence, stability, dissemination, accumulation, and the potential resulting biological activity of paracelsin with exposure to aquatic and

terrestrial organisms in the environment.

- Studies to determine the ability of the MCAN microorganism to survive in the environment relative to the survival of the unmodified parent or recipient strain, and to assess its competitiveness with other fungi in the environment. This study may require some supplementation with one or more carbon sources and the use of various soil types.
- A study to determine survival of the fungus during an anaerobic fermentation for production of ethanol by an ethanologen, and survival of the fungus during ethanol distillation or at the distillation temperature for ethanol.

CFR citation: 40 CFR 725.1080.

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 significant new uses to ensure that they are no longer reasonably foreseen to occur without first 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 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 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/tsca-inventory.*

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 March 4, 2020 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 TSCA 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 and 725.155). 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 section 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 or 725.160. 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.*

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 under docket ID number EPA–HQ–OPPT–2020–0094.

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 proposed rule would 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 Order 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.,* the Agency hereby certifies 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 would not 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 proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it 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 proposed rule.

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 Parts 721 and 725

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

Dated: February 28, 2020.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

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

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

■ 2. Add §§ 721.11459 through 721.11461 to subpart E to read as follows:

Subpart E—Significant New Uses for Specific Chemical Substances

* * * * *

Sec.

721.11459 [Reserved]

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

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

Subpart E—Significant New Uses for Specific Chemical Substances

* * * * *

§ 721.11459 [Reserved]

§ 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; CAS No. 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; CAS No. 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—[AMENDED]

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

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625(c).

■ 4. Add § 725.1080 to subpart M to read as follows:

Subpart M—Significant New Uses for Specific Microorganisms

* * * * *

§ 725.1080 Trichoderma reesei (generic).

Subpart M—Significant New Uses for Specific Microorganisms

* * * * *

§ 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);

(B) any fermentation of solid plant material or insoluble substrate to which *Trichoderma reesei* fermentation broth is added after the standard industrial fermentation is completed is initiated only after the inactivation of the microorganism as delineated in 40 CFR 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) though (c) and (i) are applicable to manufacturers and processors of this microorganism.

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

[FR Doc. 2020–05005 Filed 3–17–20; 8:45 am]

BILLING CODE 6560–50–P