

Prepublication Copy Notice:

The Acting Director of the Chemical Control Division in the Office of Pollution Prevention and Toxics signed the following *Federal Register* document on February 1, 2019:

Title: **Extension of Review Periods Under the Toxic Substances Control Act; Certain Chemicals and Microorganisms; Premanufacture, Significant New Use, and Exemption Notices; Delay in Processing Due to Lack of Authorized Funding**

Action: Notice

FRL: 9989-21

Docket No.: **EPA-HQ-OPPT-2019-0021**

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0021; FRL-9989-21]

Extension of Review Periods Under the Toxic Substances Control Act; Certain Chemicals and Microorganisms; Premanufacture, Significant New Use, and Exemption Notices; Delay in Processing Due to Lack of Authorized Funding

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Due to a partial Federal government shutdown related to the lack of authorized funding (i.e., a Fiscal Year 2019 Appropriations Bill or a Continuing Resolution), EPA is extending the review periods for all Premanufacture Notices (PMNs), Significant New Use Notices (SNUNs), Microbial Commercial Activity Notices (MCANs), and exemption notices submitted to the Agency under section 5 of the Toxic Substances Control Act (TSCA) received by EPA on or before December 29, 2018, and for which the review period had not expired as of December 29, 2018. Additionally, EPA did not receive notifications or process such submissions on or after December 29, 2018, and before the date on which the shutdown terminated on January 25, 2019, and the affected operations for the TSCA New Chemicals Program fully resumed on January 31, 2019. Also, during the shutdown, submissions made through e-PMN/CDX or other methods were not processed by EPA. Consequently, the review period for any TSCA section 5 notice submitted during the shutdown did not begin until TSCA New Chemical operations fully resumed on January 31, 2019.

DATES: The duration of this extension period is equivalent to the time period from December 29, 2018 (i.e., the date on which EPA operations shutdown) and the date on which EPA

operations for the TSCA New Chemicals Program fully resumed (i.e., January 31, 2019), or a total of 33 days.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Greg Schweer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8469; email address: *schweer.greg@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 are a manufacturer (which includes importers) or processor of a chemical substance that requires submission under section 5 of TSCA (15 U.S.C. 2604) and applicable EPA regulations. 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.

B. How Can I Get Copies of this Document and Other Related Information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0021, is available at <http://www.regulations.gov> or 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. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

Information on the shutdown can be found at <http://www.opm.gov>. Information about the TSCA section 5 requirements can be found at <http://www.epa.gov/oppt/newchems/>.

C. What is the Agency's Authority for Taking this Action?

Under TSCA section 5(c), 15 U.S.C. 2604(c), EPA may unilaterally extend the notice review period for PMNs, MCANs, and SNUNs, thereby extending the period before manufacturing or processing the subject chemical substances may begin. (See also 40 CFR 720.75(c) for PMNs and SNUNs, and 40 CFR 725.56 for MCANs.) Section 26(c) of TSCA (15 U.S.C. 2625(c)), authorizes EPA to take action with respect to a category of chemical substances; in this case, the category is all chemical substances that are the subject of the specified notices and exemption applications, for which the notice review period would otherwise expire on or after December 29, 2018. Under TSCA section 5(c), extensions of the review period for an individual TSCA section 5 notice shall not total more than 90 days. Because the extension described in this **Federal Register** notice (i.e., 33 days) is less than 90 days, EPA reserves the right under TSCA section 5(c) to issue, for good cause, future additional extensions for individual cases up to a total of 90 days.

Section 5(h) of TSCA (15 U.S.C. 2604(h)) authorizes EPA to exempt manufacturers

and/or processors of chemical substances from all or part of the requirements of Section 5 of TSCA if EPA determines that the proposed manufacture, processing, distribution in commerce, use, or disposal of such chemical substance will not present an unreasonable risk to health or the environment. Pursuant to this and other authorities, EPA has concluded that the additional time specified in this notice is required to evaluate the exemption applications described in Unit II.A. and determine whether the chemical substances that are the subject of these exemption applications will not present an unreasonable risk.

II. Extension of Review Periods

A. Which TSCA Review Periods Are Affected?

Section 5 of TSCA and 40 CFR part 720 require any person who intends to manufacture (defined by statute to include import) a new chemical substance (i.e., a chemical not on the TSCA Section 8(b) Inventory) to notify EPA at least 90 days before commencing non-exempt commercial manufacture in the form of a PMN. Similarly, at least 90 days advance notice for manufacture of new microorganisms is required under 40 CFR part 725, in the form of an MCAN. Under section 5 of TSCA and 40 CFR part 721, any person intending to manufacture or process a chemical substance for a significant new use, as designated by EPA in a SNUR, must also give EPA at least 90 days advance notice in the form of a SNUN. SNURs for microorganisms appear at 40 CFR part 725, subpart M. The required notifications initiate EPA's evaluation of the new chemical or the intended significant new use within the applicable review period. Persons may not commence manufacture of a new chemical substance, or manufacture of processing of a chemical substance for a significant new use, until EPA has conducted a review of the relevant notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

There are several of exemptions from the above-described 90-day PMN, MCAN, and SNUN notice requirements. Many of these exemptions require submitting to EPA a written notice or application, which is subject to a review period shorter than 90 days. For example, pursuant to TSCA section 5(h)(1) EPA has promulgated a Test Market Exemption (TME) from the PMN, MCAN, and SNUN 90-day notice requirements. The TME from the PMN requirement appears at 40 CFR 720.38; the TME from the MCAN requirement is codified in 40 CFR part 725, subpart F (40 CFR 725.300 through 725.370); and the TME from the SNUN requirement appears at 40 CFR 721.45(a). Under TSCA section 5(h)(4), EPA promulgated at 40 CFR 723.50 a Low Volume Exemption (LVE) and a Low Release/Low Exposure (LOREX) Exemption from the PMN requirement. The regulations at 40 CFR part 725 pertaining to genetically engineered microorganisms provide several exemptions from the 90-day MCAN requirement, including the TSCA Experimental Release Application (TERA) at 40 CFR part 725, subpart E, and the Tier I and Tier II Exemptions at 40 CFR part 725, subpart G.

B. What Action is the Agency Taking?

Effective December 29, 2018, due to the lack of authorized funding (i.e., a Fiscal Year 2019 Appropriations Bill or a Continuing Resolution), certain EPA functions were suspended. During the shutdown, no review work was performed on the TSCA section 5 notifications received by EPA on or before December 29, 2018, and for which the review period had not yet expired as of December 29, 2018. Because of the shutdown, EPA is now extending, pursuant to Sections 5(c) and 26(c) of TSCA and 40 CFR 720.75(c), the review periods of all TSCA section 5 notifications received on or before December 29, 2018, and for which the review period has not yet expired as of December 29, 2018.

The Agency requires an extension of the review periods to complete its risk assessments,

to examine its regulatory options, and to prepare the necessary documents associated with the relevant determination under TSCA section 5(a)(3). Therefore, EPA has determined that good cause exists to extend, under TSCA section 5(c), the review period for each such TSCA section 5 notification.

The duration of this extension period is equivalent to the time period from December 29, 2018 (i.e., the date on which EPA operations shutdown) and the date on which EPA operations for the TSCA New Chemicals Program fully resumed (i.e., January 31, 2019), or a total of 33 days. Although EPA reopened following the partial government shutdown on January 28, 2019, EPA set January 31 as the day that normal operations of the TSCA section 5 New Chemicals Program fully resumed. These additional days beyond January 28 reflect the additional time that was needed to ensure that: EPA data systems -were fully operational; EPA and contractor staff have ID badges, passwords and access to systems were reset; EPA and contractor staff whose 1-year approvals to access TSCA CBI expired during the shutdown were reestablished; and contractor staff who were reassigned to other contracts not affected by the shutdown were reassigned to contracts supporting the New Chemicals Program.

Under TSCA section 5(c), the total extensions of the review period for an individual PMN shall not exceed 90 days. Thus, since the extension described in this notice is for less than 90 days, EPA reserves the right to issue additional extensions under TSCA section 5(c) in the future for good cause up to a total of 90 days.

Because of these circumstances, EPA is taking the following actions and is requesting the assistance of notifiers as described in this unit:

Category 1--TSCA section 5 notices and exemptions submitted to EPA on or after December 29, 2018, and before the date on which the affected operations fully resumed on

January 31, 2019. During the shutdown, submissions made through e-PMN/CDX or other methods were not processed. Consequently, the review period for any TSCA section 5 notice submitted during the shutdown did not begin until TSCA New Chemicals Program operations fully resumed on January 31, 2019.

Category 2--TSCA section 5 exemption notices scheduled to expire on or after December 29, 2018. For any exemption notices that have not been granted by EPA and for which the review period was scheduled to expire on or after December 29, 2018, EPA is hereby extending the notice review period by 33 days (the number of days equivalent to the duration of the shutdown until affected operations fully resumed). This additional time is required to ensure there is sufficient opportunity to determine that the chemical substances that are the subject of the exemption applications will not present an unreasonable risk.

Category 3--TSCA section 5 PMNs, MCANs, and SNUNs scheduled to expire on or after December 29, 2018. For any PMN, MCAN, or SNUN for which the review period was scheduled to expire on or after December 29, 2018, EPA is hereby extending the notice review period by 33 days (the number of days equivalent to the duration of the shutdown until affected operations fully resumed).

C. Was this Action Submitted to Congress and the Comptroller General?

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before the Agency can impose binding requirements like those contained in a rule, the Agency must submit a rule report, which includes a copy of the document, to each House of the Congress and to the Comptroller General of the United States. Although this document is not a rule, it is binding in the sense that the suspensions announced in here are binding. EPA has submitted a report to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United

States prior to its publication in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

Environmental protection, Chemical, Microorganisms, Premanufacture Notices, Test Marketing Exemptions.

Dated: February 1, 2019.

Lynn Vendinello, Acting

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.