Premanufacture Notification (PMN) Requirement
For New Chemical Substances

Summary of the Requirement. Every chemical substance1 that is manufactured for commercial purposes in the United States or imported for commercial purposes is required to be listed in the USEPA’s TSCA Inventory of Chemical Substances (“Inventory”). The Inventory was established pursuant to Section 8(b) of TSCA. Substances that are not on the Inventory are considered “new”: in order to legally manufacture or import a “new” chemical substance for commercial purposes, a Premanufacture Notification (PMN) must be submitted to the Agency at least 90 days before manufacture or import begins. After receipt of a PMN the Agency has 90 days to review it, which can be extended to 180 days for “good cause.”2 This 90 to 180-day interval is known as the “review period.”

Within the applicable review period, EPA is required to make one of the following three determinations3 with respect to the new chemical substance for which the PMN was submitted:

1) The chemical substance is not likely to present an unreasonable risk of injury to health or the environment.4 If EPA makes such a determination of “not likely to present an unreasonable risk,” the submitter of the PMN may commence commercial manufacture or import of the chemical substance notwithstanding any remaining portion of the applicable review period.5 EPA is required to publish a statement of the “not likely to present an unreasonable risk” finding in the Federal Register.6

2) The chemical substance presents an unreasonable risk of injury to health or the environment.7 If EPA makes such a determination of “presents an unreasonable risk,” it is required to take certain actions under TSCA Section 5(f) to the extent necessary to protect

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1 The term “chemical substance” is defined in TSCA Section 3. Chemical substances that are not subject to TSCA include pesticides, tobacco or any tobacco product, certain nuclear materials, and any food, food additive, drug, cosmetic, etc. See TSCA Section 3 (“Definitions.”) for the precise definitions and exclusions.

2 TSCA Section 5(c).


4 In making such a determination, the USEPA is not allowed to consider costs or other nonrisk factors, but must consider an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA under the conditions of use. The term “potentially exposed or susceptible subpopulation” means “a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” The term “conditions of use” means “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” TSCA Section 3 (“Definitions.”)

5 TSCA Section 5(g).

6 Id.

7 In making such a determination, the USEPA is not allowed to consider costs or other nonrisk factors, but must consider an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA under the conditions of use. See footnote 4 for the definitions of “potentially exposed or susceptible subpopulation” and “conditions of use.”
against the unreasonable risk, and consider whether to issue a Significant New Use Rule ("SNUR").

3) A) The information available to the EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the new chemical substance; or
   (B) (I) in the absence of sufficient information to permit the EPA to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of the PMN substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment; or
   (II) the PMN substance is or will be produced in substantial quantities, and that substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

If EPA makes any one of the above determinations under the above Option 3), the Agency is required to issue an order under TSCA Section 5(e) prohibiting or limiting commercial activities to the extent necessary to protect against an unreasonable risk. The PMN submitter may commence manufacture of the new chemical substance only in compliance with the order. EPA is also required to consider whether to issue a Significant New Use Rule ("SNUR").

If EPA fails to make a determination under options 1), 2), or 3) as discussed above on a PMN by the end of the applicable review period, and provided that the PMN has not been withdrawn by the submitter, there are provisions for refunding to the submitter all applicable fees charged for review of the PMN. However, no refund will be made in the event that the submitter has not provided certain required information to EPA or has otherwise unduly delayed the process.

Within 30 days after manufacture or import begins, the PMN submitter must file a "Notice of Commencement of Manufacture" ("NOC") with EPA. Upon receipt of the NOC the Agency adds the new chemical substance to the Inventory, following which any person may legally manufacture or import the substance for any commercial purpose, subject to any restrictions or prohibitions the EPA may have specified.

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8 See TSCA Section 5(a)(3) ("Review and Determination."), and 5(f) ("Protection Against Unreasonable Risks"). EPA is required "to the extent practicable" to consult with OSHA prior to adopting any prohibition or other restriction addressing workplace exposures. See TSCA Section 5(f)(5) regarding consultation with OSHA, which was added to TSCA by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

9 TSCA Section 5(f)(4) ("Treatment of Nonconforming Uses").

10 In making such a determination, the USEPA is not allowed to consider costs or other nonrisk factors, but must consider an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA under the conditions of use.

11 See TSCA Section 5(a)(3) ("Review and Determination."), and 5(e) ("Regulation Pending Development of Information"). EPA is required "to the extent practicable" to consult with OSHA prior to adopting any prohibition or other restriction addressing workplace exposures. See TSCA Section 5(f)(5) regarding consultation with OSHA, which was added to TSCA by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

12 TSCA Section 5(e).

13 TSCA Section 5(f)(4) ("Treatment of Nonconforming Uses").

14 See TSCA Section 5(a)(4) ("Failure to Render Determination.")

15 40 CFR §720.102.

16 The PMN requirement was published as a final rule on May 13, 1983 (40 FR 21742-64), and is codified at 40 CFR Part 720. On September 13, 1983 (40 FR 41132), EPA stated that the rule would become effective on October 26, 1983, with the exception of certain provisions such as the procedural requirements concerning the Section 5(h)(3) exemption for R&D chemicals. Those provisions were clarified and published as a final rule on April 22, 1986 (51 FR 15101-03) and were incorporated into Part 720. The PMN requirements were substantially amended at 60 FR 16308ff on March 29, 1995.
Who is Subject to the Requirement? Persons intending to manufacture or import for commercial purposes a chemical substance that is not on the TSCA Inventory are subject to the PMN requirements. The Premanufacture Notification must be submitted on a special PMN form, which is reproduced on the following pages for informational purposes. All PMNs are required to be submitted to the USEPA electronically; paper forms are no longer allowed. Information that is required to be submitted on the form includes chemical identity, data on production, import and use, and information on occupational and environmental exposures. See 40 CFR Subpart C for a description of the information to be included in the Premanufacture Notice.

When Must the Notification be Submitted? The PMN Form including all required information must be submitted to the USEPA at least 90 days before commercial manufacture or import begins.

Special Notes: The PMN requirements apply only to new chemical substances and not to new mixtures, i.e., the rule pertains only to the commercial manufacture and import of new chemical molecular identities, and does not regulate the mixing of two or more chemicals, provided that a new chemical substance is not produced during mixing.

Several categories of chemical substances are not subject to the PMN requirements, even though they may not be listed in the Inventory. Such substances include impurities, by-products, non-isolated intermediates, and new substances that result from exposure of a chemical substance to environmental factors such as air or sunlight. See 40 CFR §720.30, “Chemicals not subject to notification requirements,” and the PMN Rule’s definitions of “impurity” and “by-product”.

A PMN is not required for any new chemical substance which is manufactured or imported in small quantities solely for research and development purposes. The term “small quantities” is defined as amounts “not greater than reasonably necessary” for R&D purposes.\(^\text{17}\) R&D activities include tests of the physical, chemical, production, and performance characteristics of a chemical substance,\(^\text{18}\) and include research for product development purposes.\(^\text{19}\) A company may utilize the R&D exemption without informing the Agency.

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\(^\text{17}\) TSCA Section 5 (“Manufacturing and Processing Notices”) which governs the manufacture and import of new chemical substances and significant new uses of specified chemical substances, was substantially amended in June, 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

The PMN requirement does not apply to new chemical substances that are not manufactured or imported “for commercial purposes”, e.g., any chemical which is manufactured or imported in small quantities solely for purposes of research and development. This “R&D exemption” to the PMN requirement is authorized by TSCA Section 5(h)(3), and is codified at 40 CFR §§720.36 and 720.78. Those CFR sections contain requirements for qualifying for the R&D exemption.

New chemical substances that are manufactured or imported for test marketing purposes may qualify for a Test Marketing Exemption (“TME”) from the PMN requirements. See pages A2-A3, and 40 CFR §§720.38 and 720.78 which are printed in this chapter.

In addition, the PMN requirement does not apply to new chemical substances that are manufactured solely for export, unless the USEPA finds that the substance, mixture, or article presents an unreasonable risk of injury to health within the United States or to the environment of the United States (see TSCA Section 12(a), 40 CFR §720.3(s) and 40 CFR §720.30(e)). Nor does the PMN requirement apply to chemical substances that are not subject to TSCA such as pesticides, tobacco products, foods, drugs and cosmetics (see TSCA Section 3(2) for the precise definitions of these exclusions).

\(^\text{18}\) 51 FR 15097 (April 22, 1986).

\(^\text{19}\) TSCA Section 5(h)(3) provides that:

The requirements of subsections (a) and (b) of this section do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,
that it is doing so. This is in contrast to the Test Marketing Exemption, where prior Agency approval is required. However, in order to qualify for the R&D exemption, all requirements in 40 CFR §§ 720.36 (“Exemption for research and development”) and 720.78 (“Recordkeeping”) must be followed.

EPA may grant an exemption to the PMN requirements for new chemical substances that are manufactured or imported for test marketing purposes. Test marketing exemptions (“TMEs”) must be applied for and include the information specified in 40 CFR §720.38. In order to grant a TME the Agency must conclude that: “the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application.” The EPA may impose restrictions that it considers appropriate. EPA is required by TSCA Section 5(h)(6) to either approve or deny an application for a TME within 45 days of receipt.

TSCA Section 5(e) (“Regulation Pending Development of Information”) authorize the EPA to issue an order (to take effect upon the expiration of the applicable review period) to prohibit or limit the manufacture, import, processing, distribution, use and/or disposal of a proposed new chemical substance. These “Section 5(e) orders” are required to be issued by EPA when it makes a determination under EPA’s “Option 3” described on page A2 of this chapter.

TSCA Section 5(f) (“Protection Against Unreasonable Risks”) authorizes EPA to take action upon finding that a new chemical substance presents an unreasonable risk of injury to health or the environment. After making such an “unreasonable risk” determination regarding a chemical substance for which a PMN was submitted (EPA’s “Option 2” described on page A1 of this chapter), the Agency is required to take one of the following actions “to the extent necessary to protect against such risk”: (1) issue a proposed rule under TSCA Section 6(a), which is effective upon its publication in the Federal Register; or (2) issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of the substance that is the subject of the unreasonable risk determination. Such an order “shall take effect on the expiration of the applicable review period.”

The EPA conducts inspections to assure compliance with the PMN requirements and to verify and audit PMN data submitted to the Agency. See 40 CFR Part 720, Subpart G, “Compliance and Inspections”.

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20 TSCA Section 5(h)(1) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

21 Such a USEPA order must “prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or...prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance...including while any required information is being developed, only in compliance with the order.” TSCA Section 5(e) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

22 TSCA Section 5(f)(1).

23 TSCA Section 5(f) “Protection Against Unreasonable Risks.” In a proposed rule that is issued under TSCA Section 6(a) with respect to a PMN substance, the USEPA can A) Limit the amount of a substance which may be manufactured, processed, or distributed in commerce; or B) require one or more of the actions that are described in TSCA Section 6(a)(2) – 6(a)(7). Such requirements include restrictions on particular uses of the chemical substance, minimum warning and notification requirements, restrictions on disposal, etc.

24 TSCA Section 5(f)(3)(A).