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TOXIC SUBSTANCES CONTROL ACT (TSCA)

RESEARCH AND DEVELOPMENT (R&D) EXEMPTION FOR NEW CHEMICALS

Section 5(a) of TSCA requires anyone who plans to manufacture (including import) a new chemical substance to provide the Environmental Protection Agency (EPA) with notice of the activity. This notification is referred to as a premanufacture notification (PMN). A PMN is required at least 90-days in advance of the first non-exempt commercial manufacture or import of a new chemical substance.[1] However, a substance may be exempt from the need for a PMN if the commercial activity fits within one of EPA's categorical exemptions.[2] One such exemption is the R&D exemption, the authority for which is section 5(h)(3) of TSCA. A PMN is not required:

> "with respect to the manufacturing or processing" of a new chemical substance only in small quantities "solely for the 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, if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified . . . of any risk to health which the manufacturer, processor . . . has reason to believe may be associated with such chemical substance."[3]

The implementing regulations for the R&D exemption are at 40 C.F.R. § 720.36 and 720.78. The R&D exemption is self-implementing and no advance notice or application to EPA is required. Notice under section 5 is required once the use of the chemical substance no longer fits the criteria of the R&D exemption. The R&D exemption may be used while a PMN is pending, providing the activities qualify under the exemption.

R&D ACTIVITIES AND TEST MARKETING

EPA guidance states that R&D activities are inclusive of a range of possibilities if "intended solely as scientific experimentation, research, or analysis" and that companies may evaluate "chemical or physical characteristics, the performance, or the production characteristics of a chemical substance, a mixture containing the substance, or an article."[4] R&D can be conducted in "a laboratory, pilot plant, commercial plant outside the research facility, or at other sites appropriate for R&D" and testing commercial scale production capabilities is permissible. Once the purpose of the R&D analysis and

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1 40 C.F.R. § 720.40(b).
2 15 U.S.C. § 2604(h).
3 Emphasis added. 15 U.S.C. § 2604(h)(3).
4 EPA, New Chemical Information Bulletin; Exemptions for Research and Development and Test Marketing (November 1986), https://www.epa.gov/sites/default/files/2015-08/documents/tmeranddbulletin.pdf (hereinafter, " TSCA R&D Bulletin"), pp 2 -3.

experimentation is completed, any further importation, processing, or use of the R&D substance requires that EPA complete its review of a PMN submission.

EPA's guidance distinguishes R&D activities from test marketing activities that are subject to a separate exemption authorized in section 5(h)(1) of TSCA and 40 C.F.R. § 720.38. EPA guidance provides that whereas "R&D focuses on the analysis of the chemical or physical characteristics, the performance, or the production characteristics" . . . "[t]est marketing focuses on [consumer's] acceptance of a chemical substance, and the probable demand for a product in a market where it will be competing with other goods."[5] Notification to EPA 45 days in advance of commencing a test marketing activity is required.

R&D CHECKLIST

To conduct activities that qualify for the TSCA R&D exemption, EPA specifies that companies must do the following:

1) Conduct a hazard determination: Review and evaluate the information in your possession or control to determine whether there is reason to believe there is any potential risk to health which may be associated with use of the new chemical substance (40 C.F.R. § 720.36(b)(1));

2) Provide notification of potential risks: Notify all persons in your employ or to whom the substance is distributed of the risk(s) identified and associated with the substance (40 C.F.R. § 720.36(a)(2)). This is accomplished through distribution of product with a label and safety data sheet (SDS) for the chemical substance, such as those supplied by the manufacturer of the R&D chemical;

3) Ensure proper supervision: The research must be conducted under the supervision of a technically qualified individual (TQI). (40 C.F.R. § 720.36(a)(3)). A TQI is one or more persons with the education, training, or experience to understand the health and environmental risks associated with the R&D substance (40 C.F.R. § 720.3(ee)(1)). The TQI is responsible for ensuring that appropriate methods of experimentation, analysis or chemical research are followed, and for the safety assessments and clearances related to the procurement, storage, and disposal of the substance (40 C.F.R. § 720.3(ee)(2)(3)). EPA guidance explains, with respect to the supervisory role, that a professional certification is not required and more than one such individual may supervise activities involving a particular chemical substance;[6]

4) Provide notification that use can be only for R&D to customers: If the new chemical substance is distributed, provide notice that the substance is to be used "only for R&D purposes" (40 C.F.R. § 720.36(c)(2)(i)). R&D quantities that are distributed as part of an article are exempt from this notification requirement;

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5 TSCA R&D Bulletin, Section B.3.

6 TSCA R&D Bulletin at 6.

5) Limit quantities to those necessary for research: There is no time limit associated with this exemption. The time depends on the needs and scope of the activity. The R&D chemical must be manufactured or imported only in "small quantities" that are commensurate with the R&D activity (40 C.F.R. § 720.36(a)(1)). EPA guidance instructs that "small quantities" is limited to whatever is necessary for legitimate R&D activities. Thus, depending on the type of R&D activity and its scale, the necessary quantities may actually be large. There is no numerical maximum quantity limitation providing the activity is legitimately R&D;[7]

6) Ensure proper disposal: When disposal of the R&D chemical, or mixtures or articles is necessary, applicable Federal, state, and local regulations (40 C.F.R. § 720.36(e)) have to be followed. Final disposition of the R&D chemical substance may include incorporation into an article, which can then be distributed and sold for non-exempt commercial purposes. The use of an R&D substance in this manner does not trigger PMN requirements.[8] Additionally, the exemption provides that R&D substances may be disposed of as waste, burned as fuel or reacted or processed to form other chemical substances for commercial purposes. If surplus quantities of R&D substance remain after the research is completed, those quantities may be kept and stored for future use. The surplus R&D material may be used for non-exempt commercial scale manufacture, but only after EPA's PMN review process is completed;[9] and

7) Maintain appropriate records to document compliance: Companies are required to maintain the following records for 5 years after their creation (40 C.F.R. § 720.78(b)(3)):

   a. Copies of, or citations to, information reviewed and evaluated to determine any potential risk to health associated with the R&D substance (40 C.F.R. § 720.78(b)(1)(i));

   b. The method of employee and customer notifications, including copies of any labels or written notices used (40 C.F.R. § 720.78(b)(1)(ii) and (iv)); and

   c. Records must be kept of the names and addresses of any persons other than the manufacturer whom the substance is distributed, the identity of the substance, and the amount distributed (40 C.F.R. § 720.78(b)(1)(iv)).

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[7] *Id*. at 5.

[8] 40 C.F.R. § 720.36(d). An "article" is defined under 40 C.F.R. § 720.3(c) as an item manufactured to a specific shape or design for an end-use function and maintains its shape or design or otherwise does not have a chance of chemical composition that has an independent commercial purpose.

[9] It is necessary to import new quantities of the chemical substance after the PMN review period is complete to file a Notice of Commencement (NOC) to place the chemical on the TSCA Chemical Substances Inventory. Use of R&D material that was imported prior to the end of the review period, does not meet the conditions necessary to file the NOC. 40 C.F.R. § 720.102(b)(1) specifies that the PMN submitter must submit the NOC to EPA on, or no later than 30 calendar days, after the first day of non-exempt manufacture.

These records are subject to inspection by EPA, so that when deciding where (*e.g.*, in a central location or at a specific facility) these records maintained for at least 5 years, it is important to ensure they are accessible.

R&D AND ARTICLES

The TSCA R&D exemption permits manufacturers and importers to use or sell articles incorporating an R&D chemical substance without the submission of a PMN. 40 C.F.R. § 720.36(d). Here, an "article" refers to a "manufactured item: (1) [w]hich is formed to a specific shape or design during manufacture; (2)[w]hich has end use function(s) dependent in whole or in part upon its shape or design during end use; and (3) [w]hich has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article." 40 C.F.R. § 720.3. In addition, there can be no release of the chemical from the article.[10]

Further, articles produced for R&D are not required to include any specific labeling pursuant to TSCA. Typically, a chemical substance distributed under the TSCA R&D exemption must include language notifying downstream users that the substance is for TSCA R&D only. This notification ensures that downstream users are aware of use restrictions and do not assume the chemical substance is compliant with PMN reporting. Furthermore, clear labeling allows EPA inspectors to, without delay, understand the basis underlying distribution of a liquid, powder, or solid that is not an article. Here, it is unnecessary to include the "TSCA R&D only" language because EPA will identify the distribution as exempt from notification based upon its status as an article.

R&D substances used to make an article also benefit from reduced TSCA R&D recordkeeping pursuant to 40 C.F.R. § 720.78. Recordkeeping for the R&D material is triggered when the amount of R&D substance incorporated into the article is greater than 100 kg per year. In that case, the following records must be kept: (1) identity of the substance to the extent known; (2) the production volume; and (3) the disposition of the substance. 40 C.F.R. § 720.78(b)(2). It is worth noting that the Occupational Safety and Health Administration (OSHA) also exempts articles from its Hazard Communication Standard requirement for having a safety data sheet (SDS). 29 C.F.R. § 1910.1200(b)(6)(v).

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[10] *U.S. Environmental Protection Agency, TSCA Chemical Data Reporting Fact Sheet: Articles, Response to Question 2* (Aug. 3, 2012).