

Research and Development (R&D) Exemption

Section 5(h)(3) of the TSCA allows the Administrator of EPA to develop regulations exempting manufacturers and processors of chemical substances subject to the TSCA from the notice requirements of section 5(a) if they manufacture or process the substances "only in small quantities solely for the purposes of scientific experimentation or analysis, or chemical research on, or analysis of such substance, or another substance, including such research or analysis for the development of a product." No application is required for the exemption for R&D under section 5(h)(3). Procedural and recordkeeping requirements for the exemption have been promulgated at 40 CFR section 720.3(cc), section 720.36 and section 720.78.

R&D focuses on the analysis of the chemical or physical characteristics, the performance, or the production characteristics of a chemical substance, a mixture containing the substance, or an article. It can include production of a chemical substance for use by others in their R&D. Legitimate R&D activity generally includes specific monitored tests undertaken as part of a planned program of activity. An R&D substance cannot be distributed to consumers. The burden of proving eligibility for the R&D exemption is entirely with the person claiming it. EPA advises those claiming the exemption to be prepared to justify their claim to EPA in adequate detail. In addition to the specific requirements for the R&D exemption at 40 CFR section 720.36(c)(2), that if a company distributes an R&D substance outside of its employ it must (1) notify that the use is for R&D only and (2) provide notice of any health risk, please note that 40 CFR section 720.36(c)(3) establishes that adequacy of notification is the responsibility of the manufacturer. There is no bar to your being paid for a product which is for use in R&D.

A useful discussion of the R&D exemption is found in the New Chemical Information Bulletin "[Exemptions for Research and Development and Test Marketing](#)" (1986-1, November 1986, Office of Toxic Substances), which addresses a number of the requirements for commercial R&D.

Notification to EPA in advance of manufacture of a new chemical substance is required under section 5 of the TSCA for commercial distribution of a new substance which is no longer within the ambit of the R&D exemption. Section 5 notices require you to certify that the new chemical substance will be manufactured for other than R&D purposes (although R&D work can go on for different uses than those identified in a Section 5 notice).