

TSCA Section 8(c) Recordkeeping and Reporting Fact Sheet: Limitations and Exclusions

This Fact Sheet provides guidance on specific limitations and exclusions for recordkeeping and reporting requirements under the Toxic Substances Control Act (TSCA) section 8(c). TSCA section 8(c) and implementing regulations at 40 CFR part 717 require manufacturers and certain processors of chemical substances to keep records of “significant adverse reactions” to health or the environment alleged to have been caused by the substance or mixture. This recordkeeping requirement allows the EPA access to a potentially extensive historical record of information regarding the potential effects of chemical substances as observed in real-world conditions. Records of allegations of significant adverse reactions must be maintained in accordance with 40 CFR part 717 and be available for inspection or submission to EPA upon request. The information an 8(c) call-in provides can reveal patterns of adverse effects or concerns for certain conditions of use that may not otherwise be readily apparent. Such information may be beneficial, on a case-specific basis, when considering chemical substances for prioritization, scoping, risk evaluation, and risk management, among other uses.

TSCA section 8(c) records requests may be initiated at any time and will specify which records or portion of records (e.g., those implicating a particular chemical substance) must be reported. While this fact sheet is broadly applicable to TSCA 8(c) as per the implementing regulations, the EPA may also choose to further narrow the scope of the information being requested on a case-by-case basis. Limitations may include, but are not limited to, requiring TSCA 8(c) reporting only from certain types of entities or limiting reporting based on the type of allegation or information. Please consult the applicable Federal Register Notice (FRN) to determine all appropriate chemical specific TSCA 8(c) submission requirements.

Because TSCA 8(c) submissions require assessments of the reportability of allegations of human health and environmental harm, and because a TSCA 8(c) call-in has not occurred for many years, EPA is providing this fact sheet to assist potentially regulated entities when determining whether they are subject to reporting and if so, the scope of their reporting obligation. In addition to this document, EPA is making available, for reference purposes, a historical document entitled “Questions and Answers Concerning the TSCA Section 8(c) Rule” from July 1984. *The agency is not reissuing the historical guidance and notes that it predates multiple amendments to 40 CFR part 717 and therefore some text may not accurately reflect the current regulations.*

The statutory provisions and EPA regulations described in this document contain legally binding requirements. This document does not substitute for those provisions or regulations, nor is it a regulation itself. Thus, it does not, and is not intended to, impose legally binding requirements on EPA or the regulated community, and it is not intended, nor can it be relied upon, to create any right or benefit, substantive or procedural, enforceable at law or in equity, against the Agency or any other person. Any decisions regarding a particular reporting or recordkeeping obligation will be made based on the statute and regulations.

If there are questions about TSCA 8(c) reporting and recordkeeping obligations, or potentially reportable allegations, please contact EPA's TSCA Hotline at tsca-hotline@epa.gov or 202-554-1404.

1. TSCA 8(c) Recordkeeping Required Only for “Significant Adverse Reactions”

Under TSCA 8(c), records must only be maintained for allegations of “significant adverse reactions.” The rule at 40 CFR 717.3(i) defines “significant adverse reactions” as reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment. Allegations that do not meet the definition of a “significant adverse reaction” are not required to be recorded and maintained pursuant to TSCA 8(c) and should not be reported to EPA in the 8(c) call-in.

Significant adverse reactions to human health include but are not limited to:

- (1) Long-lasting or irreversible damage, such as cancer or birth defects.
- (2) Partial or complete impairment of bodily functions, such as reproductive disorders, neurological disorders, or blood disorders.
- (3) An impairment of normal activities experienced by all or most of the persons exposed at one time.
- (4) An impairment of normal activities which is experienced each time an individual is exposed (40 CFR 717.12(a)).

Section 8(c) allegations may focus on serious health effects, but they can also report lesser effects experienced by a group of individuals or repeatedly by an individual. However, it should be noted that all significant adverse reactions alleged to have been caused by a chemical substance may not trigger TSCA 8(c) recordkeeping requirements because multiple exemptions to those requirements exist, as further explained in the following sections.

2. TSCA 8(c) Recordkeeping Exemption for Allegations Associated with Recognized Human Health Effects

The TSCA 8(c) rule allows the collection of data that may establish new links between a chemical and previously unidentified or misunderstood hazards. A body of knowledge about well-established hazards exists for many chemicals, which may be identified through publicly available sources such as Safety Data Sheets (SDS), product labeling, and scientific literature including, but not limited to, information found at the Agency for Toxic Substances Disease Registry website (<https://www.atsdr.cdc.gov/index.html>) and the EPA Integrated Risk Management System (<https://www.epa.gov/iris>). Allegations of significant adverse reactions that are commonly recognized human health effects—i.e., “known human effects” as defined in 40 CFR 717.3(c)—do not trigger recordkeeping requirements (see 40 CFR 717.12(b)) and, therefore should not be reported to EPA pursuant to an 8(c) call-in. However, the exemption does not apply if the “significant adverse reaction” was a significantly more severe toxic effect than previously described or if the reaction resulted from a lower exposure level, a significantly shorter exposure period, or a different exposure route than previously described (see 40 CFR 717.3(c)(2)).

3. TSCA 8(c) Recordkeeping Exemption for Allegations Attributable to a Federally Reported Spill or Release of a Chemical

Allegations regarding environmental effects do not need to be recorded if the alleged cause is attributable to an incident of environmental contamination that has already been reported to the federal government (See 40 CFR 717.12(d)). Specifically, pursuant to 40 CFR 717.12(d), recordkeeping requirements are not triggered if the alleged cause of a significant adverse reaction to the environment can be directly attributed to an accidental spill or accidental discharge, emission exceeding permitted limits, or other incident of environmental contamination that has been reported to the federal government under any applicable authority. Allegations associated with federally reported releases that are exempt from reporting may include but are not limited to those associated with releases from leaking underground storage tanks, releases caused by train derailments, releases caused by maritime or industrial accidents, or releases associated with Superfund sites. Note that releases reported to state regulators are not included in this exemption unless the state has been delegated oversight under federal law or implementing regulations. Note that most state leaking underground storage tank programs, and some contaminated land remediation programs have been delegated federal authorities by EPA.

4. TSCA 8(c) Recordkeeping Exemption for Extractive Industries and Sole Coincidental Manufacturers

Persons are exempt from recording and reporting significant adverse human health or environmental effects provided the means by which they manufacture a chemical substance solely involves mining or other solely extractive functions. This exemption applies to companies or sites within a company whose sole function is mining or extracting naturally occurring materials (See 40 CFR 717.7(a)(1)). In addition, the regulations exempt persons whose only manufacturing act is to produce a substance coincidentally under certain specific circumstances, as described in 40 CFR 717.7(a)(2).

5. TSCA 8(c) Recordkeeping Exemption for Sole Distributors

Sole distributors are exempt from TSCA 8(c) recordkeeping requirements (see 40 CFR 717.7(c)). A sole distributor refers to “[a] person solely engaged in the distribution of chemical substances.” A sole distributor is exempt from recordkeeping and reporting requirements unless such a person is also a manufacturer or processor subject to those requirements. For example, a “distributor” who repackages chemical substances or mixtures is considered a processor and, thus, is not a sole distributor. Sole distributors may include, but are not limited to, those firms that distribute chemical substances as described in the wholesale trade SIC codes 5161—Chemicals and Allied Products, 5171—Petroleum Bulk Stations and Terminals, and 5172—Petroleum and Petroleum Products Wholesalers, Except Bulk Stations and Terminals.

6. TSCA 8(c) Recordkeeping Exemption for Retailers

Retailers are exempt from TSCA 8(c) recordkeeping requirements unless the retailer is also a manufacturer or a processor subject to those requirements (see 40 CFR 717.7(d)). A retailer is defined as a person who “distributes in commerce a chemical substance, mixture, or article to ultimate purchasers who are not commercial entities.” (40 CFR 717.3(h)).

7. TSCA 8(c) Timeframe Exclusions

EPA may require the submission of all records that fall within the record retention period described in TSCA section 8(c) and 40 CFR 717.15(d). These include employee health-related allegations for the prior 30 years and any other record of significant adverse reactions for the past five years.

8. TSCA 8(c) Call-in for Records Implicating Specified Chemicals

Using a notice in the Federal Register, EPA may require the submission of records or a portion of records that are specific to certain chemicals, per 40 CFR 717.17(b). Thus, records or portions of records unrelated to the chemical(s) specified in a call-in notice should not be reported to the EPA in response to such notice.