

TSCA Section 8(c) Recordkeeping and Reporting Fact Sheet: Submission of Data via the CDX System

This Fact Sheet Provides guidance on the submission of Data to EP in response to a TSCA section 8(c) data call-in. All TSCA section 8(c) documents must be transmitted to the Agency electronically by the designated reporting deadlines using the EPA's Central Data Exchange (CDX) system. The CDX system is the Agency's electronic reporting site and supports over 65 environmental programs with their electronic reporting and data exchange needs. The system is used by Industry, State, Local Agencies, and Tribes to share environmental data. Most large manufacturers of chemical substances are likely to be familiar with the CDX data submission process. However, stakeholders unfamiliar with the system or who may need to establish a new CDX account can do so with the assistance of the CDX Chemical Safety and Pesticide Programs Registration User Guide, found online at <https://cdx.epa.gov/about/userguide>. The following fact sheet is intended to supplement the information provided in the User Guide and is specific to TSCA section 8(c) submissions. If there are any questions about using the CDX system or specific to submitting TSCA 8(c) records, please feel free to contact EPA's TSCA Hotline at tsc hotline@epa.gov or 202-554-1404.

1. TSCA 8(c) Submissions using CDX

Once a CDX account has been established, TSCA 8(c) respondents will transmit records of allegations of significant adverse reactions to health or the environment to the appropriate EPA office. For TSCA 8(c) submissions, you will need to have an Authorized Official for the Submissions for Chemical Safety and Pesticide Programs (CSPP) program service. On the Chemical Information Submission System screen in CDX, select the "TSCA – Communications" option from the drop-down list and click OK. Select to create a new communication. Follow the directions on the screen to create a submission passphrase. Then, in communications, select the "Section 8(c) Communication" submission type. Once you have selected the "Section 8(c) Communication" submission type, you will choose the relevant 8(c) chemical and then select from a list of identifiers to categorize the file(s) that you are submitting. Please note that the application accommodates Confidential Business Information (CBI) claims, but that a CBI claim must include a sanitized version of any document that contains a CBI claim.

2. Record Identifiers

Identifiers used within the TSCA Section 8(c) Communication dropdown menu are included below in **bold**, with a summary of the type of files that should be associated with each identifier. When multiple Record Identifier categories apply to a file, duplicative entries can be made. This summary is provided solely to assist you in properly categorizing the information being submitted. Files must contain the information described in 40 CFR 717.15(b), including the results of any self-initiated internal investigation of significant adverse reactions. Please refer to [40 CFR part 717](#) for complete details regarding the legally required information to submit to EPA.

TSCA Section 8(c) Recordkeeping and Reporting Fact Sheet: Submission of Data via the CDX System

- a) **Employee health reactions <30 years** – Use for files that relate to significant adverse reactions (as per 40 CFR part 717) to the health of employees alleged to have been caused by a subject chemical substance (including by implicating the substance as described in 40 CFR 717.10(b)(2)) for which reporting is required. Employee health-related allegations are those arising from any employment-related exposure, whether or not such allegation was submitted by or on behalf of the recordkeeper's own employee. Records must be submitted from the past 30 years.

- b) **Non-employee health reactions <5 years** – Use for any files that relate to significant adverse reactions (as per 40 CFR part 717) to human health of non-employees alleged to have been caused by a subject chemical substance (including by implicating the substance as described in 40 CFR 717.10(b)(2)). Records must be submitted from the past five years.

- c) **Animal and plant life effects <5 years (Significant Adverse Reaction to the Environment)** - Use for any files that relate to significant animal and plant life effects alleged to have been caused by a subject chemical substance (including by implicating the substance as described in 40 CFR 717.10(b)(2)). Examples include allegations of gradual or sudden changes in the composition of animal life or plant life, including fungal or microbial organisms in an area; allegations of an abnormal number of deaths of organisms (e.g., fish kills); allegations of a reduction in agricultural productivity, whether crops or livestock; allegations of a reduction of the reproductive success or the vigor of a species; and allegations of alterations in the behavior or distribution of a species. Files must be submitted even if the affected area is restricted to the environs of a plant or disposal site. Records must be submitted from the past five years.

- d) **Contamination of the physical environment <5 years (Significant Adverse Reaction to the Environment)** – Use for any allegations of long-lasting or irreversible contamination of components of the physical environment alleged to have been caused by a subject chemical substance (including by implicating the substance as described in 40 CFR 717.10(b)(2)) for which reporting is required. These effects include but are not limited to impacts to groundwater, surface water, and soil resources with limited self-cleansing capability. Records must be submitted from the past five years.

3. Batching Submissions and Data Limitations

Records transmitted to EPA via CDX will be listed under “Section 8(c)” and will be further identified by their Record Identification subcategory. Each entry can include multiple attachments and will be assigned a unique Case Number. The size of attachments is limited, so respondents may need to break their 8(c) submissions into multiple entries.

TSCA Section 8(c) Recordkeeping and Reporting Fact Sheet: Submission of Data via the CDX System

4. Noted Limitations and Exclusions

Regulations governing recordkeeping and reporting requirements under TSCA section 8(c) appear at 40 CFR part 717. When contemplating submissions, please note that 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 maintained and should not be reported to EPA in the 8(c) call-in.

Additional information on the requirements for a TSCA section 8(c) submission call-in can be found at [EPA's TSCA section 8\(c\) website](#). It is recommended that you contact EPA's TSCA Hotline at tsca-hotline@epa.gov or 202-554-1404 <mailto:TSCAtestorders@epa.gov> if you have any questions about what type of records must be submitted to EPA. about what type of records must be submitted to EPA.