Section 8(d) Health And Safety Data Reporting Requirement

Summary of the Requirement. The USEPA periodically adds chemical substances and mixtures to its “TSCA Section 8(d) List of Chemicals” which is found in 40 CFR Part 716. Persons who manufacture (including import) for commercial purposes any listed chemical or who have done so (or have proposed to do so) within 10 years preceding the effective date of the listing, have various requirements concerning the reporting of health and safety studies to the Agency. The Section 8(d) rule requires the reporting of existing studies; it does not require that new health and safety studies be conducted.1

Who is Subject to the Requirement? Manufacturers (including importers) of the chemical substances and mixtures that are specifically designated by the Agency in 40 CFR §716.120 are subject to this requirement. Processors who are not manufacturers or importers are exempt from reporting unless the USEPA specifically states otherwise in a particular TSCA §8(d) notice or rule. Distributors and retailers who are not manufacturers, importers or processors are exempt.2

What Information Must be Reported? The Rule requires reporting of either copies of health and safety studies and/or lists of such studies, depending on the circumstances (see below). The term “health and safety study” is broadly interpreted to mean any study of any effect of a chemical substance or mixture on health or the environment or both, including underlying data and epidemiological studies, studies of occupational exposure, toxicological, clinical, and ecological or other studies including data on chemical and physical properties. Prior to June 30, 1998 the USEPA required submission of all “health and safety studies” for a substance when that substance was listed in 40 CFR §716.120. However, commencing June 30, 1998 the USEPA specifies the study types and other characteristics of the studies that are required to be submitted. Certain studies are exempt from reporting, including (1) studies which have been published in the scientific literature, and (2) certain studies previously submitted to the EPA.3

1. The first Section 8(d) reporting requirement was published at 43 FR 30984 (July 18, 1978) but was subsequently revoked following a challenge by Dow Chemical Company (Dow Chemical Company v. United States Environmental Protection Agency, 605 F. 2d 672 (1979)). The rules for reporting were republished at 47 FR 38791-99 on September 2, 1982. The Section 8(d) reporting requirement was revised with respect to “automatic reporting” for ITC-listed substances and mixtures at 50 FR 34812-13 on August 28, 1985, and was subsequently revised and republished at 51 FR 32726-41 on September 15, 1986.

The Dow decision affirmed EPA's authority to obtain studies on chemicals manufactured or processed for research and development purposes, and to obtain copies of studies on a chemical from companies that do not manufacture, process or distribute that chemical. The Agency has chosen, however, not to exercise fully either of those authorities in the current Section 8(d) Rule.

The text of the Rule was subsequently amended at 52 FR 20084 (May 29, 1987) and at 52 FR 44828 (Nov. 20, 1987). The Rule was further substantially amended at 63 FR 15773 (April 1, 1998) to, among other things: 1) limit routine reporting to only manufacturers who fall within the North American Industry Classification System (NAICS) (in effect as of January 1, 1997) Sub-sector 325 (chemical manufacturing and allied products), and Industry Group 32411 (petroleum refiners); 2) exclude “processors” of listed chemical substances from routine reporting; 3) revise the types of studies and the grade/purity of the substance for which reporting is required; 4) change the Reporting Period; and 5) change the measure of adequacy of the required file search.

2. The USEPA has the authority under TSCA Section 8(d) to require reporting by distributors but has decided to exempt them from reporting. The Agency’s rationale for this exemption is that very few distributors perform health and safety studies unless they are also manufacturers or processors (47 FR 38780, September 2, 1982). Processors are exempt from reporting unless the USEPA specifically states otherwise in a particular TSCA §8(d) notice or rule (40 CFR §716.5(c)).
Detailed instructions for reporting unpublished health and safety data is provided in 40 CFR Part 716, which is reprinted on the following pages. To provide guidance, the general reporting requirements of Part 716 are listed below:

**Category 1 Persons Required to Report:**
Persons who, in the 10 years preceding the effective date that a substance is listed, either have proposed to manufacture or import, or who have manufactured or imported the listed substance must submit to EPA a copy of each health and safety study which is in their possession at the time the substance is listed.

**Category 2 Persons Required to Report:**
Persons who, on the effective date that a substance is listed, propose to manufacture or import, or who are manufacturing or importing the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time the substance is listed.

b. A list of unpublished health and safety studies known to them but not in their possession at the time the substance is listed.

c. A list of health and safety studies that are ongoing at the time the substance is listed and are being conducted by or for them.

d. A list of each health and safety study that is initiated within the Reporting Period, and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or initiated and is now complete-regardless of completion date.

**Category 3 Persons Required to Report:**
Persons who, after the effective date that a substance is listed but prior to the termination of the Reporting Period, propose to manufacture or import the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time they propose to manufacture or import the listed substance.

b. A list of unpublished health and safety studies known to them but not in their possession at the time they propose to manufacture or import the listed substance.

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3. The complete list of exemptions to the reporting requirements is found at 40 CFR §716.20.

4. Reporting Periods generally terminate 60 days after the effective date on which the chemical substance or mixture is added to 40 CFR §716.120. EPA may require reporting beyond the usual 60 day period in a rule promulgated under TSCA §8(d); however, §716.65 provides that “EPA will not extend any reporting period later than 2 years after the effective date on which a listed chemical substance or listed mixture is added to 40 CFR §716.120.”
c. A list of health and safety studies that are ongoing at the time they propose to manufacture or import the listed substance, and are being conducted by or for them.

d. A list of each health and safety study that is initiated within the Reporting Period, and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or initiated and is now complete—regardless of the completion date.

**When Must the Report be Submitted?** Unless the USEPA specifies otherwise, submissions of copies of studies and of lists of studies from persons in Category I and 2 above must be postmarked on or before 60 days after the effective date of the listing of a substance or mixture in §716.120. However, persons who first propose to manufacture (or import) a listed substance within the Reporting Period (which usually terminates 60 days following the effective date of listing), i.e. persons in Category 3 above, must submit the required copies and lists of studies within 60 days of proposing such manufacture or import.\(^5\)

Persons who first propose to manufacture or import a listed substance or listed mixture after the termination of the Reporting Period for that substance or mixture, are not required to report with respect to that substance under TSCA §8(d). However, reporting obligations may exist for such a manufacturer or importer with respect to that substance under TSCA §8(e) and under other TSCA provisions or other laws or regulations.

The only reporting requirements that do not terminate at the end of the Reporting Period apply to those manufacturers or importers who submitted to the USEPA lists of ongoing or initiated studies under 40 CFR §716.35(a)(1) or (a)(2) before the Reporting Period terminated. Copies of those studies must be submitted within 30 days following their completion regardless of the study’s completion date.

**Special Notes:** Chemicals are periodically added to the Section 8(d) List through notices published by the Agency in the Federal Register. Although the general procedure for listing is for the Agency to propose, receive public comments on, and then to finalize the addition of a chemical substance or mixture to the list (see 40 CFR §716.105(a)), certain chemicals are added automatically after action of the Interagency Testing Committee (ITC). This procedure is specified at 40 CFR §716.105(b) and (c). (For a discussion of the ITC and the TSCA chemical testing requirements, see Section IV.) Whenever the ITC recommends a chemical to the EPA, the Agency publishes a Notice to that effect in the Federal Register. The Notice sets forth the ITC Report and discusses the chemicals and studies that the Committee has recommended. Separately, and usually at a later date, the Agency publishes a Notice adding the recommended chemicals to the Section 8(d) List. Manufacturers and importers of those chemicals are required to submit studies and/or lists of studies as required by the general reporting provisions of 40 CFR Part 716.

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\(^5\) 40 CFR §716.60(a).
The latter procedure is frequently referred to as “automatic §8(d) reporting for ITC-listed substances” because of the absence of the usual public comment period of at least 30 days that allows interested persons time to question the appropriateness of adding the chemical to the Section 8(d) List. There is, however, an abbreviated public comment period of 14 days for ITC-listed chemicals that allows companies or other persons a limited time to submit information showing why a given ITC-listed substance or mixture should not be added to the list of substances and mixtures subject to reporting under §8(d).6

Automatic reporting for ITC-listed substances and mixtures is also a requirement of the TSCA Section 8(a) PAIR Reporting Rule at 40 CFR Part 712, discussed in Chapter C of this Section.7 Manufacturers and importers who are subject to automatic reporting under the Section 8(d) Health and Safety Data Reporting Rule may be subject to automatic reporting under the Section 8 (a) PAIR reporting requirement if the substance is also listed in Part 712.

6. 40 CFR §716.105(c).
7. The analogous Section 8(a) automatic reporting provision is found at 40 CFR §712.30.