Section 8(c) Recordkeeping Requirement Concerning Alleged Adverse Health Or Environmental Effects

Summary of the Requirement: Manufacturers, importers and processors of chemical substances or mixtures are required to maintain records of significant adverse reactions to health or the environment that are alleged to be caused by the substance or mixture, or alleged to be associated with its manufacture, processing, or distribution. Allegations that must be recorded include any statement of belief made by any person regarding a link between a particular company's product, process or emission and a significant adverse health or environmental effect. To be recordable, allegations need not be supported by any proof or regard for evidence.[1] Records required to be maintained include consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment. Persons required to maintain records must permit Agency inspection of the records, and must submit the records to the Agency upon request.[2]

Who is Subject to the Requirement? Manufacturers and importers of chemical substances and mixtures are subject to this recordkeeping requirement. A processor is subject to this requirement if it either 1) processes chemical substances to produce mixtures, or 2) repackages chemical substances or mixtures.

Distributors and retailers are exempt from this recordkeeping requirement unless they are also a manufacturer, importer, or a processor subject to the requirement. Manufacturers or manufacturing site activities are exempt if the means by which they manufacture a chemical substance solely involves mining or other solely extractive functions.[3]

What Information must be Recorded? Any written and signed allegation (provided that it meets the criteria below) of a significant adverse reaction to health or the environment that is received by a person who is subject to the TSCA Section 8(c) rule is required to be recorded and maintained. Manufacturers, importers, and processors have different requirements: Manufacturers and importers must maintain a record of (1) any allegation identifying a chemical substance it manufactures; (2) any allegation identifying the operations in the manufacture of any chemical substance it manufactures; (3) any allegation identifying any of its own processing or distribution in commerce activities with respect to any chemical substance it manufactures; (4) any allegation identifying emissions, effluents or other discharges from any activity described in 40 CFR §717.5(a); and (5) any allegation identifying a substance produced coincidentally during processing, use, storage, or disposal of a

1. One of the purposes of the TSCA Section 8(c) recordkeeping requirement is to provide a database to aid in identifying previously unknown chemical risks, and to reveal patterns of adverse effects that might otherwise go unnoticed for long periods of time. The records that are maintained pursuant to the requirement are thus designed to serve as an "early warning system" for chemical hazards. In order to accomplish these purposes the Section 8(c) rule "casts a broad net" with regard to allegations that must be recorded. Thus there is no requirement that, to be recordable, allegations be supported by proof or regard for evidence.
2. The Section 8(c) Recordkeeping Requirement was published as a final rule at 40 CFR Part 717 on August 22, 1983 (48 FR 38187-90). Amended at 50 FR 46769, November 13, 1985.
3. See 40 CFR §717.7 for a description of persons not subject to the Section 8(c) Requirement.

chemical substance it manufactures. Processors, on the other hand, must maintain a record of (1) any allegation identifying any mixture it produces and distributes in commerce; (2) any allegation identifying any chemical substance or mixture it repackages and distributes in commerce; (3) any allegation identifying any of its own further processing or distribution in commerce activities of the products described in (1) and (2) above; (4) any allegation identifying emissions, effluents, or other discharges from any activity described in 40 CFR §717.5(b); and (5) any allegation identifying a substance produced coincidentally during the processing, use, storage or disposal of the products described in (1) and (2) of this sentence.[4]

All written and signed allegations of significant adverse reactions must be maintained. Companies subject to the rule are not required to maintain unsigned written allegations. A company must deal with oral allegations in one of two ways: it must transcribe the allegation as orally presented to it, or alternatively, the company must inform the alleger that the allegation may be subject to the Section 8(c) requirement, and request that the alleger submit the allegation in writing and signed.[5]

Allegations concerning the health of any employee arising from any employment-related exposure must be maintained for 30 years. All other allegations must be maintained for five years.[6]

“Significant adverse reactions” are reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment.[7] Alleged significant adverse reactions to health that must be recorded 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, and (4) an impairment of normal activities which is experienced each time an individual is exposed. Persons subject to the Section 8(c) requirements are not required to record allegations of significant adverse reactions to health that are known human effects.[8]

Alleged significant adverse reactions to the environment that must be recorded include but are not limited to (1) gradual or sudden changes in the composition of animal or plant life, including fungal or microbial organisms, in an area, (2) abnormal number of deaths of organisms, e.g., fish kills, (3) reduction of the reproductive success or the vigor of a species, (4) reduction in agricultural productivity,

4. See 40 CFR §§717.5 and 717.10 for descriptions of persons and allegations subject to the Section 8(c) Requirement.
5. 40 CFR §717.10(b)(1). Requirements concerning the location and content of records maintained pursuant to the Section 8(c) rule are found at 40 CFR §717.15.
6. 40 CFR §717.15(d).
7. 40 CFR §717.3.
8. 40 CFR §717.12. “Known human effects” are defined in 40 CFR §717.3. The Agency has stated that the exclusion for known human effects applies strictly to effects observed in or known to occur in humans. Results of in vitro testing or animal testing related to the substance in question may not be considered the equivalent of a known human effect. EPA has given the following example: a company cannot decide to exclude from its records an allegation that a substance caused sterility in a worker solely because the scientific literature contains studies showing that the substance caused sterility in laboratory animals. 48 FR 38180 (August 22, 1983).

whether crops or livestock, (5) alterations in the behavior or distribution of a species, and (6) long-lasting or irreversible contamination of components of the physical environment. However, firms are not required to record a significant adverse reaction to the environment if the alleged cause of that reaction can be directly attributable to an accidental spill or other accidental discharge, emission exceeding permitted limits, or other incident of environmental contamination that has been reported to the federal government under any applicable authority.[9]

Is There a Requirement to Make the Records Available for Agency Inspection or to Submit the Records to the Agency? Firms must make records of allegations available for inspection by any duly designated representative of the Administrator. There is no provision for automatically reporting the records to the Agency; rather, EPA will issue a letter or a notice in the Federal Register specifying which records must be submitted.[10]

Special Notes: In order to help illustrate the operation of the Section 8(c) Rule, the following table of hypothetical examples has been published by the Agency.

Hypothetical Examples

Source: 48 FR 38181 (August 22, 1983)

Fact situation	Recordable under Section 8(c)?	Comment
(1) Several workers submit a report claiming that working around the chemical W gave them "blue lips".	No	"Blue lips" or methemoglobinemia is a known human effect of exposure to chemical W at the level and route of exposure experienced by the workers.
(2) One worker writes that whenever he is required to work around chemical W he has experienced severe nose bleeds.	Yes	Nose bleeds are not a commonly recognized reaction to chemical W exposures. The reaction is experienced each time the individual is exposed.
(3) A worker writes that on several occasions when he has worked with chemical X he has experienced tingling fingers and nausea. The literature states that these reactions are known to occur at exposure levels above 100 parts per million in the workplace air. However, the plant monitoring records show that levels of chemical X in the air do not exceed 20 parts per million.	Yes	Even though the reported reaction is a "known human effect" the worker seems to be repeatedly experiencing the reaction at a much lower exposure level than existing information indicates.

9. 4O CFR §717.12.

10. 40 CFR §717.17. The first call-in of Section 8(c) records concerned perfluoroalkyl resins. The requirement to submit those records was contained in an EPA letter dated April 21, 1986, which was sent to a number of manufacturers and processors.

Fact situation	Recordable under Section 8(c)?	Comment
(4) On a day when the temperature was 98°F, a plant neighbor calls the company to complain that something in the air is making him sick. A company official asks that the allegation be submitted in writing but nothing is subsequently received.	No	The company chose to ask the alleger to submit this oral allegation in writing. Since nothing was received, no further action by the company is required.
(5) A farmer writes to a chemical plant that his farm pond seems to have become contaminated from the company's waste disposal facility located adjacent to his property. The farmer alleges that his cattle, whose only water source is this pond, have experienced several stillbirths and one case of deformed hooves. Sampling records of test wells at the facility showed no significant level of leachate.	Yes	The report cites reproductive disorders or birth defects in livestock alleged to have been caused by a "discharge" from a disposal facility. This may represent a hitherto undetected problem of environmental contamination.
(6) After beginning work on a new process involving chlorinated compounds, a worker alleged that she contracted painful sores on her face that lasted several days, causing her to miss work.	Yes	Even though an apparent one-time occurence, the reaction was a substantial impairment of normal activities. Also, the reaction is suggestive of chloracne, an indicator of a potentially more serious effect.
(7) The family of a long-time company employee writes that they believe the employee's lung cancer was caused by his many years of work around chemical Y. The company health records show that the employee did not evidence adverse symptoms during his employment but he did smoke cigarettes. Chemical Y is, however, a suspected human carcinogen.	Yes	Even though chemical Y is a suspected human carcinogen the report cannot be excluded on this basis. Further, it cannot be excluded on the supposition that smoking was the sole cause of the cancer or that it may have enhanced the carcinogenic properties of chemical Y. The company may, however, place in the file evidence of the smoking as a potential mitigating factor.
(8) A consumer writes that she got a skin rash the first time she used the company's new detergent.	No	There is no evidence that the rash occurred repeatedly or that the product was used more than once. Also, there was no indication that the rash was an impairment of the consumer's normal activities.

Fact situation	Recordable under Section 8(c)?	Comment
(9) A consumer writes that even with proper ventilation (recommended), he got dizzy and nauseous the three times he used the company's furniture finish remover.	Yes	The repeated nature of the reaction makes it recordable along with the fact that the reaction was an apparent impairment of normal activities. The reaction apparently is not a "known human effect" under the exposure conditions associated with use in accordance with the product's labelling.
(10) A neighbor of a chemical plant writes that on May 15 he saw numerous dead fish as well as an oily film covering the water downstream from the plant. On May 13 the plant had experienced a ruptured wasteline pipe that allowed concentrated waste to enter the river. The spill was duly reported to the state and to EPA.	No	This environmental reaction appears to be directly attributable to an incident of environmental contamination already reported to EPA.