United States Environmental Protection Agency

Office of Toxic Substances 401 M Street S.W. Washington. DC 20460

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Questions and Answers Concerning the TSCA Section 8(c) Rule

Questions Received at: Seminar on Toxic Substances Control Act Section 8(c) Recordkeeping and Reporting Allegations of Adverse Reactions November 10, 1983

QUESTIONS AND ANSWERS
CONCERNING THE TSCA SECTION 8(c) RULE

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Section 8(c) Recordkeeping and Reporting
Allegations of Adverse Reactions
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PREFACE

On August 22, 1983 EPA promulgated a rule that implemented section 8(c) of Toxic Substances Control Act (TSCA). This rule requires manufacturers and certain processors of chemical substances and mixtures to keep records of "significant adverse reactions" alleged to have been caused by such substances or mixtures.

EPA's Office of Toxic Substances (OTS) sponsored a national conference on the section 8(c) rule on November 10, 1983. The conference drew well over 500 registrants, who represented the chemical industry, government, and public interest groups. During the conference attendees were encouraged to submit written questions. EPA staff representatives attempted to answer as many of these questions as time would allow. However, the volume of questions received dictated that OTS publish this Question and Answer document. This is the second Question and Answer document on the section 8(c) rule. The first such Question and Answer document was published in November 1983 and made available to the conference attendees and any other interested persons.

For further information about the TSCA section 8(c) rule please contact:

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ALLEGATIONS SUBJECT TO THE RULE

1. Is it necessary for us to keep all allegations, or must we verify that the allegation meets the definition contained in the rule? Who determines what constitutes a significant adverse reaction? Do customer incidents involving human and environmental exposure, even if they are unremarkable, need to be kept? In the case of a human reaction, is a doctor's report required?

Answer:

You are only required to keep those allegations that have been determined to meet the definitions, including a significant adverse reaction, that are contained in the rule. This determination is made by the person subject to the rule. Consumer allegations involving human or environmental reactions are recordable. Again, companies have the right to compare the stated reaction to the definitions in the rule. No doctor's report is required, and, in general, no proof or evidence is required to be included in an allegation for it to be recordable.

2. May several identical or very similar allegations received over a short period of time (i.e., a week or two) be recorded as a single allegation?

Answer:

You must record and file allegations individually.

3. If allegations are made as a result of unusual circumstances, for example, misuse, spills, and accidents, are these recordable?

Answer:

In such cases, the known effects exemptions may apply. If the allegations indicate that the reaction occurred as a result of exposure from use not in accordance with the labeling, then this may be an exempt allegation. (See 40 CFR 717.3(c)). If the environmental reaction can be attributed directly to an incident of contamination already reported, then this may not be a recordable allegation (See 40 CFR 717.12(d)).

4. In a situation where a company receives an allegation naming a specific material or process, but there is no evidence that the material can cause the significant adverse reaction, is the allegation recordable?

Answer:

Yes. In general, proof or evidence that a material can cause a significant adverse reaction is not required.

5. Are allegations which do not cite a specific substance, material, process, or effluent required to be recorded? Sometimes plant neighbors provide very vague and general complaints, such as: the plant fumes burn my eyes and throat; the plant emissions smell terrible; I'm afraid to drink my well water; or, the plant odors aggravate my sinuses, allergies, or asthma. Are these types of allegations recordable?

Answer:

Some link between the significant adverse reaction and a company's product must be made. Allegations must implicate the product by naming a specific substance, or an article or mixture containing a substance, by naming a process or operation in which substances are involved, or by identifying an effluent, emission, or other discharge from a site of manufacturing, processing, or distribution of a substance or mixture. Several of the above examples relating to plant effluents could be recordable because they indicate the plant's air emissions and cite a reaction that impairs normal activities.

6. Are allegations which incorrectly identify the cause required to be recorded?

Answer:

Allegations must be recorded based upon their contents. Once filed, you may not remove an allegation from the file as a result of further investigation. The results of the subsequent investigation (e.g., that the company believes the cause was incorrectly identified) may be placed in the allegation file.

7. Are unsigned union grievances relating to a specific substance recordable?

Answer:

No. Companies are not required to file an unsigned written allegation.

8. If an employee says “the normal chemicals don’t bother me, but, boy the fumes from that one process do,” is this a recordable/reportable allegation? What if he is a heavy smoker with known respiratory impairment?

Answer:

First, an allegation citing a process is potentially recordable. The fact that the alleger is a heavy smoker is not relevant to whether the stated reaction is recordable.

9. If an employee of a user of a chemical makes an allegation, is the allegation subject to recordkeeping?

Answer:

Yes. This is a potentially recordable allegation. Any person may make an allegation.

10. If an employee allegation implicates a proprietary mixture made by another company and the mixture contains a material made by your company, is the allegation recordable?

Answer:

This is potentially a recordable allegation, and should certainly be reviewed by the receiving company as such. Generally, an allegation of this type should be sent to the manufacturer of the mixture. However, if the alleger specifically implicates the mixture component made by your company as the cause of the significant adverse reaction, you should keep the allegation.

11. When one of our employees makes a statement alleging a health effect during the course of a medical examination, is this an 8(c) allegation or is it protected as confidential medical information, or both?

Answer:
Provided the employee statement meets all of the criteria for a recordable allegation as stated in the rule, this type of statement is potentially recordable. In so far as the confidentiality of medical records is concerned, when reporting is required the alleger's identity will most likely not be part of the abstract of the allegation that would be reported to EPA.

12. If early signs of a health effect (such as elevated protein in the urine) are found during a medical surveillance program, must this be recorded as an allegation?

Answer:
Isolated medical data are not inherently allegations. If a doctor were to make an allegation (i.e., a statement or assertion) on behalf of a patient, such data could be cited as the significant adverse reaction.

13. In cases where a medical effect is identified without the employee's knowledge, can the employer make an allegation on behalf of an employee?

Answer:
Employers can make allegations on behalf of employees. However, consciously depriving an employee of information of a potentially recordable significant adverse reaction could expose an employer to legal liability.

14. A 75 year old retiree (30 years company service) writes a letter to the company that he has lung cancer and his doctor says it is due to his past asbestos exposure as a plant mechanic engaged in asbestos insulation removal. Is this recordable under section 8(c)?

Answer:
Unless the company is also the producer of the asbestos material in question, that employer would not be the person required to keep the allegation under section 8(c).

15. Does an allegation of an adverse reaction where a mixture of standard chemicals is identified require recording under section 8(c)?

Answer:

Yes, this is a recordable allegation. A mixture can be cited as the cause of a significant adverse reaction. The fact that the mixture components are "standard" chemicals has no bearing on the recordability of the allegation.

16. If a firm is an 8(c) manufacturer, but purchases a solvent and uses it to manufacture another product, is an allegation concerning the solvent considered recordable?

Answer:

No, provided the allegation specifically cites the solvent. In such cases the Agency strongly encourages the company to forward the allegation to the solvent supplier.

17. Is there a responsibility for recording allegations received from parties to whom a substance has been exported?

Answer:

Yes, provided the allegation meets the requirements of the rule.

RESPONSIBILITY FOR RECORDKEEPING

1. Do employees have a personal liability or is the 8(c) rule a corporate responsibility?

Answer:

As discussed in section 717.3(f) of the definitions in the final rule, the term “person” refers to the business entity (e.g., company, corporation, etc.) subject to the rule. Recordkeeping is the responsibility of the “person” subject to the rule. Under certain circumstances, personal liability may be attributed to corporate officials as representative of the entity. There is case law addressing this issue.

2. Is there a small company exemption to keeping 8(c) records?

Answer:

No. Small businesses are not exempt under the provisions of the law.

EPA USE OF REPORTED INFORMATION

1. How does EPA intend to use these 8(c) files that are required to be kept by industry? How will the collection of this information prove helpful to employees or other individuals?

Answer:

While employees do not necessarily have direct access to company 8(c) files they may petition the Agency to collect and release such information. Also, the existence of this requirement in itself provides added assurance that a serious work or consumer complaint will be recognized and retained by the industry. EPA expects that individual companies will use the 8(c) records to identify problems associated with the chemicals that they manufacture, and will subsequently take steps toward resolving identified problems. EPA will use the 8(c) records to compliment other information already in our possession in order to enhance our problem identification/definition activities for new and existing chemicals. We also expect that some 8(c) notices will result from 8(c) recordkeeping. As 8(c) recordkeeping becomes established, EPA may initiate retrospective reviews to identify trends or patterns that require further attention. The 8(c) records will also be used in problem definition activities to compliment the information base for ongoing assessments under TSCA sections 4, 5, and 6.

2. Will EPA have an evaluation program to ascertain the value of this rule?

Answer:

Yes. EPA plans to investigate company recordkeeping experiences and the content of 8(c) files sometime in 1985.

3. Does OSHA have access to 8(c) records? Who, besides EPA, has access to these records:

Answer:

Only EPA has statutory authority to require access to or reporting of 8(c) records. However, once such records are obtained by EPA they become subject to release by EPA except as protected by the confidential business information provisions of TSCA (40 CFR Part 2).

REPORTING PROCEDURES

1. Please describe procedures for reporting allegations to EPA. How often and by what mechanism will EPA request industry to submit copies of allegations? How will EPA decide what type of allegations are to be reported?

Answer:

The reporting requirements of the rule are described in section 717.17 of the final rule. The level of reporting will be dependent on the Agency's information needs, plus the number of requests for this information from other interested parties. EPA plans to use one Federal Register Notice to require reporting of records relating to several different substances.

2. Under the proposed regulation would a company be required to forward records to EPA if three (3) or more allegations on air emissions (odor complaints) are received? How will EPA respond if no allegations have been recorded during the interim between inspections?

Answer:

This question seems to relate to the "automatic reporting" provision that was included in the 8(c) rule proposed on July 11, 1980 (45 FR 47008). EPA included this provision as a topical area for further comment. This provision has been removed from the final rule pending further investigation.

3. What responsibility does the company have if the central files are unintentionally destroyed or lost?

Answer:

Information on file remains the responsibility of the company for the retention period, 5 or 30 years, as specified by the rule. Unintentional loss or destruction of section 8(c) files will be handled on a case-by-case basis by EPA's Compliance Monitoring Staff.

4. If EPA decides to call in allegations on a specific substance, will all mixtures containing any amount of that substance be subject?

Answer:

In general, EPA will require reporting of significant adverse reactions that implicate a chemical substance in question. If a company has recorded a significant adverse reaction alleged to have been caused by a mixture, and the substance in question is a known component of the mixture, then that record may have to be reported. EPA's reporting notice will specify whether allegations relating to mixtures must be reported.

5. Are there no requirements under 8(c) for reporting allegations against chemicals distributed in the U.S. by a firm who has imported the chemical

a. if manufactured abroad by parent, subsidiary, or otherwise "group" companies?

b. if manufactured abroad by totally unrelated company?

c. if manufactured abroad by fellow operating companies?

Answer:

Under TSCA, import is equivalent to manufacture. Therefore, the importer of chemical substances or mixtures must keep records of allegations of significant adverse reactions relating to those imported substances or materials. The location and corporate relatedness of the original manufacturer of the substance or mixture are irrelevant.

6. Do reporting exemptions for previous reporting to Federal agencies apply only to environmental effects, or also to health effects reporting to OSHA or CPSC?

Answer

There are no reporting exemptions, only exemptions from having to record a significant adverse reaction (See 40 CFR 717.12).

REPORTING UNDER OTHER LAWS

1. How will the rule interact with TSCA section 9 and with the existing OSHA and NIOSH regulations (29 CFR 1904) requiring employers to maintain records of employee exposures to hazardous substances in the workplace.

Answer:

The 8(c) rule requires records to be kept based upon allegations rather than specific evidence. OSHA records can be filed for known effects for which there is a standard. A NIOSH health hazard investigation can be conducted in similar circumstances as an allegation might be recorded (at the employee's request to NIOSH), but with an 8(c) allegation, there is no requirement for investigation. The 8(c) rule is primarily concerned with recordkeeping. It should be noted that OSHA and NIOSH regulations are employee-related; the 8(c) rule extends into environmental areas where there is no similar precedent.

2. Are allegations by employees also considered employee health or exposure records under OSHA regulations?

Answer:

Allegations are subject to other regulations only as far as they meet the criteria contained in those other regulations.

3. Does an allegation have to be made known to all employees under RTK (right-to-know) or OSHA's Hazard Communication Rule?

Answer:

There is no such requirement in the 8(c) rule. However, EPA does encourage alleger feedback.

4. Do reporting requirements of FIFRA replace TSCA 8(c) or is compliance with both required?

Answer:

Compliance with both is required. The 8(c) rule does not pre-empt any other regulation.

5. What overlap problems exist between 8(c), 8(e), OSHA, and CPSC requirements? How should employers address these problems--particularly those concerning access requirements for medical and exposure information?

Answer:

OSHA, CPSC, and 8(e) rules are primarily reporting, while 8(c) is a recordkeeping rule. Criteria for 8(e) reporting include: there must be evidence of substantial risk of injury to health or the environment, and the source of the evidence is designed, controlled studies, or reports strongly implicating that a chemical causes serious health or environmental effects. Criteria for OSHA records include: records or reports of proven occupational illness or mechanical injury, the reactions are well recognized, usually acute effects, and reports cover workplace incidents and are kept by all businesses with more than 10 employees. Criteria for CPSC section 15 reporting include: the information must reasonably support a "substantial product hazard," the rule applies to consumer products, and covers manufacturers, distributors, and retailers of consumer products.

Some of the salient features of the 8(c) rule that differentiate it from other regulations are: 8(c) is a recordkeeping, rather than a reporting rule; allegations do not require any proof or evidence, nor must they support any conclusions; allegations must be kept only by chemical manufacturers and certain processors; OSHA, CPSC, and 8(e) reports are unlikely to contribute to an 8(c) allegation, but an 8(c) allegation could contribute to OSHA, CPSC, or 8(e) reporting; recordkeeping is limited to TSCA covered chemicals, mixtures, and articles; and known effects are exempt.

6. Will these rules affect the partial administrative stay on employee access to medical records? This stay was granted to Flower and Fragrance industry on 10/80 -- expires 2/1/84.

Answer:

There is no provision in the 8(c) rule for access to medical records.

7. Should a copy of an employee's allegation be kept in his medical record file?

Answer:

This is not a requirement of the 8(c) rule. Including a copy of the allegation in an employee's medical record is not prohibited by the rule.

REPORTING REQUIREMENTS

1. How does this regulation apply to Department of Defense installations?

Answer:

The regulation applies to persons who manufacture, process, or distribute chemical substances for commercial purposes. The Department of Defense does not engage in these commercial activities. Government-owned company-operated facilities, however, are subject to the rule in cases where they are manufacturing or processing substances for an immediate or potential commercial advantage at such plants. The operating company must therefore keep the 8(c) records.

2. Is a report of a Superfund site enough to supplant the requirement to record environmental effects?

Answer:

Yes, provided the report of Superfund site meets the criteria set forth in section 717.12(d) of the rule. That section states that “Firms are not required to record a significant adverse reaction to the environment if the alleged cause of that significant adverse reaction 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.”

3. Is an incident of environmental contamination exempt from recording requirements if it has already been reported to a state or local government?

Answer:

No, unless such state or local government has been delegated responsibility under Federal law or implementing regulations.

RECORDING PROCEDURES

1. TSCA 8(c) regulations require background or supporting data to be included in the file along with the original allegation. These data are to include sex, route of entry, etc. If this information is not included in the original allegation, does the company have an obligation to contact the alleger to determine this missing information?

Answer:

No. Section 7l7.l5(b)(iv) of the rule requires this information if ascertainable. This primarily applies in situations where the company already has this information on employees. These data may be used for future epidemiology studies that the Agency might conduct. This information must be included if it is available; companies do not need to make extraordinary effort to determine this missing information.

2. For a plant subject to 8(c), would all worker's compensation claims need to be reviewed to determine if there is a recordable allegation?

Answer:

Yes. However, it is not necessary to review worker's compensation claims submitted prior to November 21, 1983.

3. Is there any prohibition to recording the ethnic background of the alleger in the allegation record? Some known health effects have been shown to influence different ethnic groups in different ways.

Answer:

Recording data of this sort is neither required nor prohibited by the rule. However, the possible difference in effect between different ethnic groups is not a factor that should be considered in retaining an allegation. The allegation must be evaluated based upon its content.

4. Would an allegation on a mixture be an allegation on each component of the mixture if a specific substance is not identifiable as the cause of the effect?

Answer:

If you or the alleger cannot attribute the reaction to a component of a mixture, then the allegation should be filed as an allegation implicating the mixture. However, if EPA requires reporting on a chemical that you know to be a component of that mixture then the record implicating the mixture may have to be reported. The mixture reporting issue will be dealt with on a case-by-case basis.

5. How is confidential employee information handled (such as employee medical information)?

Answer:

When reporting of allegations is required, EPA will most likely ask for the abstract of the allegation (see section 7l7.15(b)(2)). This abstract does not require the specific identification by name or other identifying information of any individuals; therefore the confidentiality of a person's medical record should not be of immediate concern.

6. Is there a requirement to inform allegers about what must be contained in a written allegation?

Answer:

No. However, EPA strongly encourages companies to have some form of employee education program about the rule.

7. Is it true that a manufacturer that is not a processor within the identified SIC codes need only record adverse health or environmental allegations relating to the specific products it manufactures (as opposed to chemicals it may use in the manufacture of its product)?

Answer:

Companies are required to keep allegations relating to only the products that they themselves manufacture or process. If the allegation specifically identifies a product that the company does not make, the company is not required to keep the allegation. In such cases, EPA encourages the passback of the allegation to the company which supplied the material.

8. May the required records be kept in a computer database or would the company also be required to maintain the original, signed, hard copy?

Answer:

A company may certainly elect to establish a computer database to assist in the management of allegation records. This is not required by the rule. If a company does elect to establish a computer database, the orginal or a microfiche copy of the actual allegation must also be kept. A computer database is not suitable as a replacement for hard copy.

9. The Seminar Booklet, under “Speaker Slide Section,” lists “causes” categories -- can these be used by affected manufacturers to retain the allegations as required (i.e., substance, mixture, article, process, and discharge)?

Answer:

Filing allegation records by “causes” is an acceptable system of record-keeping.

10. Has EPA considered requiring a keyword system for recordkeeping? The cross-referencing of generic, brand, or trade names could be helpful in studying impact of a chemical in the future.

Answer:

EPA intends to continually revisit the recordkeeping provisions of this rule. At the present time, indexing allegations by keywords is not a requirement of the rule. EPA does recommend that companies maintain some system for cross-referencing allegations, so that, when reporting is required, all appropriate allegation records can be identified.

PUBLIC ACCESS TO 8(c) RECORDS

1. Would the public have access to a company's 8(c) file through a Freedom of Information request to the EPA?

Answer:
Yes, but only if the Agency had the information in its possession at the time the request was received.

2. How would an alleger know if his or her allegation was actually recorded by the company, beyond a mere verbal statement by the company?

Answer:
The rule does not contain any provision requiring alleger feedback although EPA encourages companies to inform allegers of the disposition of their allegations. Individuals may write EPA to request that a company report allegation records relating to a particular substance or mixture.

3. What is the company's responsibility to unions, employees, etc., for "Access to Records?" For example, if the union wanted a copy of all the filed allegations, do we have to give the reports to them, and if so, within what time frame?

Answer:
The rule does not require companies to provide access to allegations to anyone other than the EPA Administrator or appropriate designee, nor does the rule confer any additional powers to unions, employees, or other groups for access to company files.

MULTI-SITED CORPORATIONS

1. If some plant sites are clearly covered under 8(c), does this automatically make the entire corporation (all plant sites) covered under 8(c)? Our chemical manufacturing plant is a wholly owned facility of a large textile, fabric, etc., manufacturer. Does this rule apply only to "our chemical plant" or to the parent company as a whole?

Answer:

The entire "corporate person" is subject to the rule, even if only one plant site is engaged in activities subject to the rule. Corporate responsibilities in situations where less than all sites of a multi-site firm are engaged in 8(c) activities are discussed in section 717.5 of the rule.

2. My company is engaged solely in mining activities. My company is, however, a wholly owned subsidiary of a corporation that manufactures chemical substances. Must my company implement an 8(c) compliance program to cover complaints that may be received concerning parent company activities?

Answer:

As the "person" subject to the rule, the parent company is responsible for directing 8(c) recordkeeping activities of subsidiary operations. The subsidiary does not have direct responsibility under the rule. Parent companies, where subsidiary operations can be expected to receive allegations, should have a policy whereby the subsidiary can forward the allegation for recordkeeping by the parent.

3. If the U.S. manufacturing facility is a subsidiary of a foreign corporation, what are the reporting and recordkeeping responsibilities of the parent company to the U.S. subsidiary?

Answer:

In this situation, the U.S. subsidiary is the "person" subject to the rule. Foreign companies are not subject to the TSCA 8(c) rule, and are not accountable for keeping records of allegations.

4. In the case of a foreign subsidiary which processes/manufactures chemical substances identical to the U.S. parent, are allegations received by the foreign subsidiary considered as received by the U.S. parent and thus subject to the rule? Does this answer change with degree of U.S. parent involvement in foreign subsidiary?

Answer:

Allegations received by the foreign subsidiary are considered as received by the U.S. parent. This answer does not change with the degree of U.S. parent involvement in the foreign subsidiary.

5. As a fully integrated oil company (from wellhead to service stations) we need to know where 8(c) requirements begin and end. For example, are our service stations included (or exempted as retailers)? Is a petroleum extraction site exempt?

Answer:

A manufacturer is responsible for collecting allegations with respect to its distribution in commerce activities. Because the service stations are distributing the corporation’s manufactured and processed substances, any allegation arising from that distribution is potentially recordable, and subsidiary retailers such as service stations are not exempt. In situations where the sole operation of a company site is the extraction of a naturally occurring material, the extractive industry exemption (Part 717.9(a)) would apply.

6. Please confirm whether records must be maintained at each manufacturing plant of a multi-site corporation or at a central location. If the latter, is the corporation free to select the preferred location?

Answer:

Records of allegations are required to be maintained at one central location. EPA’s rationale for this requirement is to simplify reporting and inspections under this rule. The corporation is free to choose the central recordkeeping location. If it chooses to, the corporation may also keep copies of allegations at other sites in addition to the central location.

DEFINITIONS

1. Where does “extraction” stop and “processing” begin?

Answer:

Persons are exempt from the rule provided the means by which they manufacture a chemical substance 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. EPA considers extraction to be a primarily mechanical process such as crushing, grinding, drying, milling, leaching, etc. These are normal steps taken to remove raw materials from the earth, and prepare it for distribution in commerce as a “raw material.” Operations beyond this point, such as distilling, refining, smelting, etc. are processes of separating out marketable fractions, and are considered processes covered by the rule. They are in fact primary chemical manufacturing activities that make a person subject to the rule.

2. EPA has not defined “chemical substance” in this particular rule. Please clarify this definition. Does it differ from definitions given in previous section 8 rules?

Answer:

The term “chemical substance” is defined in section 3 of the Toxic Substances Control Act. The definition given in the Act is not changed for this rule or for other section 8 rules.

4. Does EPA consider the mixing and use of chemicals which do not react with one another to be a “manufacture” subject to the rule?

Answer:

The mixing of chemicals is both processing of chemical substances as well as the manufacture of a mixture. In general, mixture manufacture may be best thought of as a subset of all processing activities. As such only mixture manufacture to produce SIC 28/2911 type products is subject to the rule if this is all the firm does (i.e., it is not also a manufacturer of one or more of the chemical substances that comprise the mixture). This differs from “manufacture” of a chemical substance because all manufacturers of chemical substances are subject to the rule without regard to SIC code.

4. Is a repackager of bulk chemicals for resale considered to be a manufacturer or a processor for 8(c) purposes?

Answer:

Persons who repackage chemicals for resale are considered processors under TSCA.

LAWSUITS AND LEGAL ACTIONS

1. Is a lawsuit or other legal action that meets the criteria of an 8(c) allegation recordable under 8(c)? Do all the resulting legal documents have to be included in the recordkeeping file? If so, does this mean that discovery papers (often dozens of boxes of paper) constitute "subsequent investigation," which also must be recorded?

Answer:

Any lawsuit or other legal action that otherwise meets the criteria of an 8(c) allegation is recordable under the rule. Technically, all of the discovery papers in the case also constitute part of that allegation. However, it is sufficient to place a reference to the litigation files in the specific allegation record, so that, in the event of an investigation, the discovery files can be located.

2. Does a lawsuit constitute an allegation if no specific chemical is stated as the cause of an adverse reaction?

Answer:

In order to constitute a valid allegation, the allegation, among other things, must implicate a substance by naming a specific substance, mixture, process, emission, etc. This criterion applies to lawsuits as well as any other allegation.

3. Are employees protected against recrimination for submitting an allegation, particularly employees not protected by 11(c) of the OSH Act?

Answer:

Employees who submit allegations to their employer are protected from recrimination by section 23 of TSCA.

THE RELATIONSHIP BETWEEN SECTION 8(c) AND SECTION 8(e) RULES

1. What distinguishes 8(e) from 8(c)? What are the similarities and differences?

Answer:

The 8(c) rule is primarily a recordkeeping rule, while 8(e) is a reporting requirement. The 8(c) rule requires that allegations of significant adverse reactions to health or the environment be kept, whereas section 8(e) requires that evidence of substantial risk of injury to health or the environment be reported to EPA. The source of the data handled under these two provisions is also different; allegations are likely to be received from workers, consumers, and plant neighbors, while 8(e) submissions will result from designed, controlled studies and reports strongly implicating a chemical. Section 8(e) health effects submissions focus on serious health effects. Section 8(c) allegations may focus on serious health effects, but can also report lesser effects experienced by a group, or repeatedly by an individual. Both rules contain exemptions; 8(c) exempts known human effects in the scientific literature, material safety data sheets, or labeling, 8(e) exempts effects reported to EPA under other acts, and known effects in the scientific literature.

2. When does an allegation of significant adverse reaction 8(c) become subject to 8(e)?

Answer:

EPA believes that section 8(c) records will be one of several sources of information that can provide “reasonable support for the conclusion that a substance poses a substantial risk to health or the environment.” It is conceivable that just one recordable significant adverse reaction could be the trigger. Much depends on the content of the allegation. It is perhaps, more reasonable to expect that a pattern of effects recognized from the accumulation of several allegations will, in combination with other data, such as the results of a company investigation of the allegations, lead to the determination that an 8(e) notice must be submitted.

3. The first videotape spoke of a 15-day time clock. What exactly must be accomplished in that time period?

Answer:

Reporting of the section 8(e) notice to EPA must be accomplished in this 15 working day time period. It begins when a person in the company obtains the information -- i.e., has possession of or knows of the information. This person is someone “capable of appreciating the significance of the pertinent information,” to use the words of the section 8(e) policy statement. Please refer to the March 16, 1970 edition of the Federal Register for this detailed policy statement (43 FR 11110).

ORAL ALLEGATIONS

1. If a company requests that allegations be submitted in writing, does the request to put an allegation in writing have to be written?

Answer:
No.

2. My company already has a system of recordkeeping for some oral allegations (not related to 8(c) concerns). Am I prevented from requiring that oral allegations be submitted in writing for purposes of the rule?

Answer:
In the case of oral allegations, firms may choose to either transcribe the allegation into written form or request that the alleger submit a written, signed copy of the allegation. Companies can determine, on an individual company basis, how they wish to receive allegations.

3. If a company requests a written statement from an employee/consumer and that individual refuses to provide the statement, is the allegation then deemed non-recordable?

Answer:
There is a difference between “refusal” (i.e., a defiant response to the request to write down the allegation) and a non-response. If a company requests that an oral allegation be put in writing, and the alleger never submits the written allegation, the company cannot take any further steps toward evaluating such allegation for recordkeeping. If, for example, the request is made in a face-to-face meeting with an employee and that person refuses to write the allegation and insists that the company transcribe it, EPA encourages the company to transcribe the allegation.

4. If a company has a written policy of accepting only written complaints for purposes of section 8(c), what should be done with telephone calls from plant neighbors alleging a significant adverse reaction? Should the complaint be investigated by the company and then written up by the company if it meets 8(c) criteria?

Answer:
Companies should either ask for a written, signed copy of the allegation or transcribe the oral allegation. There is no requirement to investigate the allegation.

5. Can an alleger be asked to sign the company's transcription of an oral allegation? Is an unsigned written statement valid? What is a company's liability or responsibility if the alleger refuses to sign?

Answer:
There is no requirement that company transcriptions of oral allegations be signed by the alleger. Only written allegations submitted by or on behalf of an alleger must be signed. An unsigned company transcription of an allegation is valid.

6. Can a company elect to transcribe employee oral allegations while requiring others to submit written allegations?

Answer:
Yes.

7. If the company transcribes an oral allegation, but cannot identify the alleger, is the allegation recordable?

Answer:
Yes.

8. Would an unsigned transcript of an oral allegation be submissible evidence or testimony if a series of allegations lead to a lawsuit?

Answer:
The acceptability of allegations as evidence or testimony in lawsuits does not fall under the scope of the 8(c) rule.

9. When our employees are “off-duty” -- for example, at home or a party, are they required to accept allegations? Are statements made at social gatherings, public meetings, etc. that allege a chemical or process caused a health or environmental effect allegations?

Answer:

Allegations may require action under section 8(c) only if received by the “person” subject to the rule (i.e., the company). EPA could not impose 8(c) responsibilities on company employees who have no knowledge of or responsibility concerning section 8(c). Thus, in most instances allegations made to “off-duty company employees at social gatherings would not be received” within the meaning of 8(c). Officials with knowledge of a company’s 8(c) responsibilities could request that the alleger submit the allegation in writing or otherwise contact him or her during regular business hours.

SELF-INITIATED INVESTIGATIONS

1. Where does “self-initiated investigation” start? Is it a review of the allegation or is it a more formal follow-up investigation to develop more data or information?

Answer:

A “self-initiated investigation” would be an information gathering exercise beyond the point of deciding whether or not to record the significant adverse reaction allegation. The decision to keep or not to keep a particular allegation must be based upon an evaluation of the content of the allegation as received. Once recorded an allegation cannot be removed from the file based on the results of further investigation. However, if the company’s initial decision was not to record, but they initiate an investigation anyway and discover a situation that is recordable, then they are not prevented from revising the original negative decision.

2. By results of self-initiated investigation, can we assume that this does not mean the details of the investigation? Is this in fact a summary statement of results?

Answer:

A summary statement of the results of the self-initiated investigation should be placed in the allegation file. It is not necessary to keep all of the details of the investigation as part of the allegation.

3. What are the recordkeeping requirements for an investigation into an allegation that is subsequently determined to be non-reportable? If you should decide that an allegation need not be recorded and kept, how should this negative decision be recorded and how long should this be kept?

Answer:

Again, a “further investigation” is not to be used as a basis for the initial decision not to record. If a company determines that the allega-tion on its own merits does not meet the requirements of the 8(c) rule, the company need not keep the allegation. A company can, of course, keep everything it receives, but this is not required by the rule. Retaining a record of a non-recordable allegation (and investigations thereon) should be governed by the judgment of the company and its normal business practices.

4. If a company leans toward filing all or most allegations but doesn’t investigate them, isn’t the company open to criticism for not investigating? Many of the allegations may be of dubious validity, however, creating a catch 22 situation.

Answer

EPA will certainly not be critical of a company that chooses to file most or all allegations it receives - i.e., to be overly cautious in its implementation of the section 8(c) rule. A “catch 22” situation does not exist since investigation of an allegation beyond the decision to keep the allegation is not required by the rule.

PASSBACK OF ALLEGATIONS

1. We manufacture chemical mixtures from purchased raw materials. If the end user reports an adverse reaction, are we responsible for recordkeeping requirements?

Answer:
Yes. Manufacturers of mixtures are persons subject to the rule.

2. Is a company responsible for recording allegations against a starting material which is produced overseas?

Answer:
Under this rule, companies who import substances are considered the manufacturer of that substance. Companies who receive allegations on products that they import must keep those allegations.

3. Can distributors who are independent, but handle our products merely to provide smaller packages, send allegations back to us and thereby discharge their responsibilities?

Answer:
There is no provision which discharges repackagers from their responsibilities under this rule. However, if the allegation specifically cites the substance or mixture being repackaged, then this allegation can be forwarded to the supplier.

4. Should an allegation about a raw material used in the manufacture of pesticides, and/or drugs be kept with the pesticide/drug producer or should it be passed back to the raw material supplier? If the raw material was used for a non-pesticide/drug use, would the answer be different?

Answer:
In either case, the person subject to the rule may forward the allegation to the supplier of the raw material if the allegation specifically cites the raw material as the cause of the reaction. The only exception would be the case where the person subject to the rule is also the importer of the raw material.

5. If company B makes a mixture of products manufactured by company A, are both required to keep records? If not, which should keep them? Should they report allegations to each other?

Answer:

In the specific example given above, company B should keep all allegations concerning the mixture. Company A should keep all allegations on specific mixture compounds. There is no requirement that the companies report to each other, but they may find it in their best interest to do so.

6. Many of our raw materials are purchased from several different suppliers. In some instances, the same substance might have been purchased from as many as three or four different suppliers. In the case of an allegation naming a product that is purchased from more than one company, how can the exact source of the effect be identified? Do we pass the allegation back to all of the suppliers?

Answer:

In cases of multiple suppliers of the same material EPA encourages allegation passback to all suppliers.

EMPLOYEE/PUBLIC AWARENESS

1. Please expand on statements about informing employees of the 8(c) rule (i.e., cite page and paragraph of 8(c) or preamble). Does this mean those who might receive allegations or does it include those who may make them? There is no specific requirement for this specified in the rule; is this an interpretive requirement or merely a recommendation? Would notification by way of a company bulletin board be sufficient?

Answer:

EPA strongly encourages companies to inform their employees about the section 8(c) rule. However, there is no specific requirement in the rule that a company implement an employee awareness program. EPA views this as an educational activity separate from or in addition to the training of those company officials who must implement the firm's rule compliance policy.

2. Does informing all employees include those employees who would not be expected to receive or initiate a report? (Secretaries, clerks, laborers not in chemical areas). If manufacturing operations are located in one plant apart from other business operations, must employees in all locations be informed of 8(c)?

Answer:

EPA recommends that such a voluntary employee awareness program be directed toward all employees of plant sites engaged in activities covered by the rule.

3. Does the rule require notice to foreign plant employees of 8(c) reporting rules?

Answer:

Again, the rule does not require such notification but EPA recommends it.

4. How will consumers or the general public be informed of this regulation?

Answer:

EPA is developing outreach materials to inform the public of the 8(c) rule. These materials will include brochures and a videotape presentation. Companies will be contacted when such materials are available because they will provide an effective way to carry out an employee awareness program.

NOVEMBER 21, 1983 EFFECTIVE DATE

1. Recordkeeping for TSCA 8(c) starts from November 21, 1983. Are allegations made before this date recordable?

Answer:

Recordkeeping for this rule applies to all allegations received on or after November 21, 1983. Allegations received before that date are not required to be kept. If a company has, as a course of business, been keeping allegations received before the rule's effective date, EPA encourages those companies to incorporate them into its 8(c) file.

2. If a lawsuit is filed prior to the effective date but is still being litigated on the effective date is this recordable?

Answer:

No. EPA considers the filing date of a lawsuit to be equivalent to the receipt date of an allegation. Again, however, the Agency encourages companies to add such allegations to their file.

SUBSTANCES COVERED

1. Are bacteria or other living organisms considered chemical substances?

Answer:

Yes, under TSCA living organisms are considered chemical substances.

2. Are allegations on mixtures exempt from 8(c) recordkeeping? Doesn't TSCA only control new chemicals and not mixtures of known chemicals?

Answer:

Allegations on mixtures are not exempt from 8(c) recordkeeping. TSCA covers mixtures as well as new and existing chemicals, therefore, allegations received on mixtures of new or existing (known) chemicals, as well as single substances, are potentially recordable. The 8(c) rule language specifically states that manufacturers, processors, and distributors of chemical substances and mixtures are covered.

3. Is a naturally occurring substance (e.g., an enzyme) which is not required to be listed on the Inventory, but which is commercially produced and marketed, covered under the 8(c) rule?

Answer:

First, the question must be clarified. What the questioner refers to as "required to be listed on the Inventory" can have two meanings. First, "naturally occurring" substances were not required to be reported for the initial TSCA Inventory. EPA added many such naturally occurring substances on its own during the creation of the Inventory. This does not mean, however, that the enzyme in question is TSCA exempt. Only those substances, mixtures, and articles with uses exempted by section 3 of TSCA (e.g., foods, drugs, cosmetics, medical devices, pesticides, firearms, etc.) are not ultimately subject to the section 8(c) rule. For example, if the enzyme is a component in a laundry detergent then it is a TSCA covered substance for that application. Second, if the questioner implies that an enzyme with a TSCA application is not subject to the premanufacture notification review procedure then this is an incorrect assumption.

4. Is a service compound, such as a reactor cleaner, a processed material if emptied to waste disposal?

Answer:

No. In this case, the substance is not processed for commercial purposes. Disposal-only activities do not constitute manufacturing or processing for commercial purposes. The only possible exception would be if the user is also the producer of the reactor cleaner.

5. Does the importing of primary metals (SIC 33) fall under 8(c)?

Answer:

Yes. The importation of chemical substances is considered manufacture under TSCA. Primary metals are chemical substances.

FIFRA/FDA COVERED PRODUCTS

1. Are drugs or pesticides already regulated under FDA or FIFRA which are also used for other purposes subject to 8(c)?

Answer:
Yes, provided that the other use is a TSCA use.

2. Are allegations related to intermediates, processes, discharges, and emissions from plants manufacturing and processing pesticides or pharmaceuticals required to be recorded under 8(c)?

Answer:
In the manufacture and processing of pesticides, everything up to the packaged, registered pesticide product is regulated by TSCA except for intermediates that are also registered pesticides. In the manufacturing and processing of pharmaceuticals, only the wastes are considered chemical substances covered by TSCA.

3. Are treated process effluents for fully FDA or FIFRA regulated processes exempt from recordkeeping?

Answer:
No. Effluents (treated or not) from both FIFRA and FDA regulated processes are covered by TSCA and therefore subject to 8(c) recordkeeping.

4. If a chemical is manufactured solely for use as an intermediate in production of a drug, cosmetic, or pesticide, but the intermediate is not regulated by FDA, is this chemical covered by TSCA and subject to 8(c)?

Answer:
Pesticide intermediates are subject to 8(c) recordkeeping unless the intermediate is itself a registered pesticide. Intermediates in the production of drugs or cosmetics are not subject to 8(c) recordkeeping.

5. Is a plant engaged in manufacturing pesticides automatically exempt from 8(c) regulations, even if the plant also produces other chemicals (e.g., solvent recovery, waste materials, etc.)?

Answer:

No. With the exception of the end product (registered pesticide), the manufacture of pesticides is regulated by TSCA. The examples of waste materials and solvent recovery processes are covered by the 8(c) regulation.

6. Are new R & D chemicals being developed for use in pesticides (i.e., not yet FIFRA registered or even under an EUP) excluded from 8(c)? These are not “commercial” chemicals and would be in small volume. Do the regulations under discussion affect the research laboratories of a drug company involved in the development (and sometimes limited production) of pharmaceutical dosage forms?

Answer:

Research and development chemicals being developed for use in pesticides are covered by the 8(c) rule because they are not yet a registered pesticide. Research and development chemicals in general are not exempt from the 8(c) rule. However, a drug research laboratory is not likely to be affected by this rule because such activities are considered covered by FDA.

7. Is the manufacture of polymers for use in medical devices exempt?

Answer:

In general, polymer manufacture is regulated by TSCA and covered by the 8(c) rule. The manufacture of polymers for use in medical devices would be exempt from 8(c) provided the entire process was regulated by FDA. Otherwise, only those portions of the manufacturing process that are regulated by FDA are exempt from TSCA.

EXTRACTIVE INDUSTRY EXEMPTION

1. Are companies or processing facilities that mine and process (e.g., crush, grind, dry, package, etc.) naturally occurring materials covered by 8(c)?

Answer:

Mechanical mining and processing type operations such as crushing, grinding, drying, milling, leaching, flotation, liquid separation, etc., are not covered by 8(c). These are considered normal processes to remove naturally occurring materials from the earth; they are steps taken to clean the material and produce the proper size ore. Operations beyond this point such as distilling, refining, and smelting are a function of separating out marketable fractions from the raw material and are considered processes covered by the rule.

2. Is it true that a mining company which extracts a mineral from the ground and beneficiates it prior to sale is a “manufacturer” subject to the rule?

Answer:

Not necessarily. If extraction and basic ore clean-up are the sole activities, then the company is exempt. If the company takes further steps to produce chemical substances from the beneficiated ore, such as by chemical reaction, smelting, or other refinement processes, then the company would be covered by 8(c).

3. Does 8(c) cover sites with mining SIC codes whose end products are established metals, minerals, and non-metals that are regulated by Mining Safety and Health Administration (MHSA) recordkeeping and reporting rules of human health effects under 30 CFR 50.20?

Answer:

Many of the sites (either in whole or in part) covered by mining SIC codes may be subject to the “extractive industry” exemption. The exemption would not apply to the company as a whole if further processing or refining (except for basic ore clean-up) is carried out at such sites.

RESEARCH AND DEVELOPMENT CHEMICALS

1. Are all chemicals used in research and development facilities exempt under 8(c)?

Answer:

Companies are required to keep allegations on the substances and mixtures that they produce even if for the purposes of research and development. If the firm performing the research and development is not the manufacturer of the chemicals used, allegations regarding those chemicals would not be recordable by the research and development facility. Those allegations should be recorded by the firm who supplied the substance.

2. Are allegations on experimental research and development chemicals covered under 8(c)?

Answer:

Yes. Allegations on research and development chemicals are recordable by the firm that manufactures or processes them. There is no exemption for research and development. The R & D process is covered by the definitions of “manufacturing for commercial purposes” or “processing for commercial purposes.”

TOXICOLOGY LABORATORIES

1. Is an independent toxicology lab covered by the 8(c) rule in that it may be an extension of the manufacturer by contract?

Answer:

No, if by “independent” one means a toxicological testing facility that is not owned or controlled by a person subject to the rule. A testing contract would not meet the definition of owned or controlled.

2. Are contract toxicological laboratories conducting various toxicology studies on TSCA regulated chemicals not required to report adverse reactions to the manufacturer but just encouraged to do so?

Answer:

The results of toxicology studies are not allegations. However an employee at a contract toxicological laboratory can make an allegation that a substance being tested affected human health or the environment. That individual or the employing laboratory is encouraged to send that allegation to the supplier of the material.

3. Is a manufacturer of diagnostic kits using other manufacturers chemicals (repackaging) covered by 8(c)?

Answer:

If such kits are medical devices or supplies regulated by FDA and the company is not otherwise involved in the manufacture or processing of such substances for a TSCA use, then the company is exempt from the section 8(c) rule. Otherwise, repackagers are covered by 8(c).

MISCELLANEOUS SIC 28/2911 COVERAGE ISSUES

1. We are a manufacturer of flexible polyurethane foam and consider ourselves to be in SIC 3079 - miscellaneous plastics and rubber - are we covered by 8(c)?

Answer:

Yes. The manufacturing of plastics and rubber is the manufacturing of chemical substances and is covered by the rule. The 28/2911 SIC categories only apply to processors - not manufacturers of chemical substances.

2. Our company makes non-edible sausage casings under a USDA approved system and are not classified under SIC 28/2911. We react woodpulp with various, chemicals and extrude the obtained biocase under acid conditions. Are we subject to the rule?

Answer:

Yes. The process described above constitutes the manufacture of a chemical substance. Again, the 28/2911 SIC categories should not be considered limiters in the case of manufacturing.

3. If service stations are not owned by an oil company but just supplied with their product, are they covered under 8(c)?

Answer:

No. Service stations and other firms engaged in strictly retail business are not covered by the 8(c) rule. Retailers are covered by the rule if they are a subsidiary of a firm that is subject to 8(c) but even then, they would not themselves be the record holder.

4. Are refiners which are only fuel producing operations without petrochemical operations covered under 8(c)?

Answer:

Yes. Such refineries are manufacturing chemical substances and thus are covered by the 8(c) rule.

5. Would an “importer” of an article containing a toxic substance (i.e., brake linings containing asbestos) who “uses” such an article (i.e., attaches the brake linings to an automobile) be subject to 8(c)?

Answer:

No. The importation of articles is not covered under the 8(c) rule. Importation of chemical substances and mixtures, however, is considered manufacture under TSCA and is subject to the rule.

6. Is the nuclear weapons industry required to report allegations on classified materials produced for use in weapons?

Answer:

The nuclear weapons industry is exempt from the rule under the provisions of TSCA section 3(2)(8)(iv).

7. Does the regulation apply to the following industries:

- Ferrous and/or non-ferrous foundries;
- Pulp and paper manufacture;
- Semiconductor manufacture; and/or
- Printed circuit boards--telecommunications equipment?

Answer:

The regulation definitely applies to the first three listed industries. They are engaged in the manufacture of a chemical substance. If the producer of printed circuit boards and telecommunications equipment is also engaged in the manufacture of one or more substances incorporated into such articles, then such a company is covered by section 8(c). If only circuit boards are produced, section 8(c) does not apply.

KNOWN EFFECTS EXCLUSIONS

1. Must all known effects be on safety data sheets, on labels, or known to the company?

Answer:

To be exempt, a known human effect must be a commonly recognized human health effect resulting from exposure to a substance, as described in the scientific literature, in product labeling, or in material safety data sheets. Allegations regarding environmental effects do not have to be recorded if the alleged cause is attributable to an incident of environmental contamination that has already been reported to the Federal government.

2. If a company's material safety data sheet (MSDS) includes warnings about adverse reactions noted in animals, can you safely say this was a known human effect and therefore not subject to this rule?

Answer:

No. In order for the known effects exemption to be applicable, the effect must be known to occur in humans. However, in the first Q&A document on this rule the Agency did state that acute effects (e.g., acid or caustic burns or other strong primary irritant properties) demonstrated only in animal tests may be considered known human effects because of the inevitability that such substance will have similar adverse acute effects on human tissue.

3. If new information about a known effect is reported in an allegation, is this allegation recordable?

Answer:

Yes. The known effects exemption does not apply if the reaction was a significantly more toxic effect than previously reported, or if the reaction resulted from a lower exposure level, a shorter exposure period, or a different exposure route than previously reported.

4. If a product alleged to have caused a “reaction” is a mixture of many compounds but the reaction is only “known” for one of the components, is this recordable?

Answer:

Yes. The product alleged to have caused the adverse reaction must be the same as the substance or mixture for which there is a known human effect. In the example above, the effect is only known for one of the constituents of a mixture. To be an exempt known effect, the observed effect must be known for the mixture~.

5. Suppose IARC or another standard reference states “element and its compounds are probably carcinogenic to man”, but a company interprets the literature differently and believes only certain compounds or processes produce a risk. Must the company record allegations on the compounds it considers safe?

Answer:

Yes. The known human effects exemption applies to effects that are known to occur in humans. If a substance is believed to be safe, but the company receives an otherwise valid allegation, that allegation must be kept.

6. If a chemical has known health effects, and these effects are described in product bulletins, labels, etc., and precautions are also given, yet a serious adverse reaction occurs, is any resulting allegation recordable?

Answer:

No, provided the serious adverse reaction that occurs is a known human health effect and provided the allegation does not involve new information as discussed in the response to question 3.