TSCA §8(e) Questions & Answers
Published by the USEPA and dated September 2006

Definition of Substantial Risk

Q.1. How does "substantial risk" under TSCA §8(e) differ from other types of risks addressed by TSCA?
A.1. "Substantial risk" is defined in Part V of the 2003 TSCA §8(e) Reporting Guidance as a risk of considerable concern because of (a) the seriousness of the effect, and (b) the fact or probability of its occurrence. Unlike "unreasonable risk" under TSCA, economic or social benefits of use or costs of restricting use are not considered when determining whether there is reasonable support for a conclusion of "substantial risk" for purposes of §8(e).

Q.2. If a company obtains new human exposure-related information on a chemical it manufactures, such as blood or urine monitoring data on a chemical known to have serious toxic effects, is it reportable under TSCA §8(e)?
A.2. Yes. If the new information on a chemical known to have serious toxic effects indicates a level of exposure previously unknown to the Administrator, it should be reported. Information that corroborates known exposure levels, such as those within the range of chemical blood levels and other biological monitoring data recorded in the NHANES (National Health and Nutrition Examination Survey) data base, is not reportable. The Centers for Disease Control and Prevention's "National Report on Human Exposure to Environmental Chemicals" derived from NHANES is available at: http://www.cdc.gov/exposurereport.

Reporting Procedures and Responsibilities

Q.3. Does the TSCA §8(e) reporting obligation include the requirement to actively search for substantial risk information or to request it if a person knows of such information that is not in his or her possession?
A.3. TSCA §8(e) applies to information that a person possesses or has obtained. It is not intended to compel searches for information or extraordinary efforts to acquire information. However, "known" information includes information that a prudent person similarly situated could reasonably be expected to know. Negligence or intentional avoidance of information does not release a person from his or her TSCA §8(e) obligation.

Q.4. What is the time requirement for reporting supplemental information obtained after an initial TSCA §8(e) notification or for responding to an EPA inquiry for additional information following a §8(e) notice?
A.4. The information should be reported to EPA within 30 calendar days, the same as the initial §8(e) reporting requirement, unless additional time for reporting has been granted.

Q.5. Is the TSCA §8(e) guidance issued by EPA binding on persons subject to this reporting requirement?
A.5. No. While the need to report substantial risk information to EPA under TSCA §8(e) is a binding requirement (pursuant to TSCA §15(3)(B)), the policies outlined in the guidance are not a binding requirement. The June 3, 2003, TSCA §8(e) Policy Statement and Guidance (68 FR 33137) sets forth Agency guidance to aid in complying with this section of TSCA, but the §8(e) guidance published or publicized by the Agency does not impose any binding requirements on the regulated community. The June 3, 2003 guidance document articulates EPA's preferences for how and where TSCA §8(e) notices should be submitted, but it does not obligate submitters to comply with these preferences. Persons with general or specific questions on the applicability of TSCA §8(e) are welcome to contact EPA. In responding to inquiries, EPA will consider the June 3, 2003, Reporting Guidance but this guidance will not be determinative. The Agency will also consider this guidance for enforcement purposes.

Q.6. If a company has several health and safety studies on different chemicals to submit under TSCA §8(e) as a result of an acquisition or self-audit, should they be submitted to EPA as a single TSCA §8(e) submission with endpoints consolidated by chemical?
A.6. No. EPA prefers that separate submissions be provided for each chemical substance or mixture. For example, including more than one study report per submission relating to a particular chemical or mixture is acceptable, whereas submitting studies on different chemicals in a single TSCA §8(e) submission is not

appropriate. Studies on different chemicals should be submitted as different TSCA §8(e) submissions because it would be cumbersome to track many chemicals per submission in EPA's document tracking systems, such as the Toxic Substances Control Act Test Submissions (TSCATS) data base. The same reasoning applies to "For Your Information" (FYI) voluntary submissions, which should also be submitted separately for each chemical.

Persons Subject to TSCA §8(e) Reporting

Q.7. Do contractors, consultants and independent laboratories have a TSCA §8(e) reporting responsibility?
A.7. No. If they do not manufacture, process or distribute in commerce TSCA chemical substances or mixtures, they do not have a TSCA §8(e) reporting responsibility. Rather, their client manufacturers, processors and distributors are responsible for reporting such information.

Information "Known to the Administrator"

Q.8. Does EPA consider releases reported to the National Response Center (NRC) "known to the Administrator" for TSCA §8(e) purposes?
A.8. Yes. But under TSCA §8(e), only emergency incidents of environmental contamination should be reported to the NRC. As explained in Part IX. (f) of the June 3, 2003, Republication of TSCA Section 8(e) Policy Statement and Guidance, persons should report emergency incidents of environmental contamination (Part V. (c)) to either the EPA Administrator or to the NRC by telephone as soon as obtaining knowledge of the incident. Information properly filed as emergency reports to either of these parties need not be reported further under TSCA § 8(e). However, any new substantial risk information concerning the incident that is later obtained is reportable under TSCA §8(e). Non-emergency situations involving environmental contamination (Part V. (b)(1)) do not require reporting to the NRC under TSCA §8(e), but subject persons should report environmental contamination information to the EPA Administrator within 30 calendar days of obtaining it if it meets TSCA §8(e) reporting criteria. Information otherwise required to be reported to EPA, other federal regulatory agencies or states with delegated programs within 90 days for non-emergency situations involving environmental contamination or within 30 days for other types of information described under Part V.(a) and (b) need not be separately reported under TSCA §8(e). Examples of mandatory reports to the National Response Center or other authorities under a federal statute that need not be reported under TSCA §8(e) include:
Reports of releases of reportable quantities (RQs) of CERCLA §102(a) hazardous substances (reportable under 40 CFR part 302);
Reports of spills to navigable waters or adjoining shorelines of oil in quantities that may be harmful to public health or welfare, or to the environment, under the Clean Water Act and Oil Pollution Act (reportable under 40 CFR part 110 for oil discharges and 40 CFR 116 for hazardous substances discharges); and
Reports of incidents involving hazardous materials regulated by the Department of Transportation under the Hazardous Materials Transportation Act (reportable under 49 CFR part 171 for the transportation of hazardous materials, 49 CFR part 191 for natural gas and other gases transported by pipeline, and 49 CFR 195 for liquids transported by pipeline).

Q.9. Part VII. (f) of the June 3, 2003, Republication of TSCA Section 8(e) Policy Statement and Guidance states that substantial risk information need not be reported under TSCA §8(e) if it "is information of the kind under Part V. (b)(1) and (c) submitted to the Federal government or a state that is developed in connection with an authorized (by the relevant Federal or state authority) site remediation program." What is an authorized (by the relevant Federal or state authority) site remediation program?
A.9. EPA considers all federal and state corrective actions, monitoring, cleanup and remediation programs as "authorized site remediation programs" if such programs are established and enforced under federal or state laws or programs under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) or the Resource Conservation and Recovery Act (RCRA). These activities include site remediation undertaken voluntarily but with state knowledge under a specific, authorized state program, as well as remediation activities conducted pursuant to orders or enforceable agreements.

Q.10. EPA manages the Underground Storage Tank (UST) program (40 CFR Part 280) by approving state programs to operate in lieu of the Federal program. Some state programs are approved by the Agency and some are operating under a "Memorandum of Agreement" with EPA. Is reporting to a state UST program operating under either of these conditions considered "known to the Administrator"?
A.10. Yes. All information submitted to states under an UST program approved by or operating under a "Memorandum of Agreement" with EPA is considered "known to the (EPA) Administrator". Such information does not need to be reported under TSCA §8(e), as long as it is reported within the timeframes stated in Part VII. (d) of the June 3, 2003, Reporting Guidance (i.e., within 90 days for non-emergency contamination situations; immediately for emergency incidents of environmental contamination; and within 30 days for other substantial risk information).

Q.11. A chemical plant does toxicity testing on plant effluents to monitor the quality of treated wastewater to comply with permit requirements under the Clean Water Act (CWA). Are the results of such testing reportable under TSCA §8(e)?
A.11. No. Any significant toxicity findings in this context are presumed to be reportable to federal or authorized state permit authorities under the National Pollutant Discharge Elimination System (NPDES) requirements within appropriate timeframes and are covered under Part VII. (c) and (d) of the 2003 TSCA Section 8(e) Reporting Guidance regarding information that need not be reported under TSCA §8(e). However, reporting under TSCA §8(e) should be considered if additional information on the plant effluents, such as unexpected persistence, bioaccumulation or widespread contamination, are available that were not considered in setting the CWA permit.

Q.12. If EPA shares responsibility for implementing a program (e.g., sharing primacy under the Underground Injection Control Program or a site remediation program), does reporting to the state under these programs fall within the exemption for TSCA §8(e) reporting outlined in Part VII. (d) of the 2003 TSCA Section 8(e) Reporting Guidance?
A.12. Yes. Such programs are considered authorized or delegated programs for purposes of Part VII. (d) of the 2003 TSCA Section 8(e) Reporting Guidance.

Q.13. Does reporting to state emergency response committees (SERCs) and local emergency response committees (LEPCs) fall under the category of information that need not be reported under TSCA §8(e)?
A.13. Emergency incidents involving environmental contamination reported to state emergency response committees (SERCs) are exempt from TSCA §8(e) reporting, provided SERCs report to the National Response Center (NRC). The June 3, 2003, Republication of TSCA Section 8(e) Policy Statement and Guidance does not mention local emergency response committees (LEPCs) under the reporting exemptions. However, if LEPCs report to SERCs that in turn report to the NRC, they would be covered by the reporting exemption described in Part VII. (d) of the June, 2003, §8(e) guidance.

Q.14. Information that meets the TSCA §8(e) reporting criteria for non-emergency situations of chemical contamination will be submitted to EPA within 90 days to comply with mandatory reporting provisions under the Federal Water Pollution Control Act. Does the information also have to be submitted under TSCA §8(e)?
A.14. No. This information would not need to be reported under TSCA §8(e) according to Part VII. (c) of the 2003 TSCA Section 8(e) Reporting Guidance. If the same information were submitted to a state in lieu of EPA, it would be exempt under Part VII. (d) of the Reporting Guidance.

Health and Environmental Effects

Q.15. How does EPA define a "health and safety study"?
A.15. TSCA §3(6) defines a "health and safety study" as any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical or mixture, toxicological, clinical, and ecological studies of a chemical or mixture, and any test performed pursuant to TSCA. EPA believes that information and underlying data associated with a chemical or mixture known to be of considerable concern to health or to the environment may be relevant to the adverse effects of the chemical or mixture. Therefore, incident information, exposure studies, and their underlying data should be considered covered under the term "health and safety study."

Q.16. Does §8(e) of TSCA intend the submission of animal test data: (a) when a determination of "substantial risk" has been made, or (b) where merely a finding of positive animal test results useful in the further assessment of human risk has been determined?
A.16. TSCA §8(e) requires the timely submission of information (including preliminary information) from animal studies on a chemical in commerce that implicates the tested chemical as causing toxic effects of concern when there is also an exposure concern (except for serious toxic effects as noted below). The decision to report should not hinge in any way on a judgment about the relevance of the findings to an assessment of human risk. For the most serious toxic effects (e.g., cancer, neurotoxicity, birth defects), the decision to report should not even depend on a judgment of actual or potential exposure to the chemical. The mere fact that the chemical is in commerce constitutes sufficient evidence of exposure. (See the June, 2003, TSCA Section 8(e) Reporting Guidance Part V. (a).)

Q.17. When should the results of cancer bioassay studies that show significant increases over controls in benign but not in malignant tumors be submitted to the Agency under TSCA §8(e)?
A.17. Benign tumors should be reported when either statistically or biologically significant increases over controls are observed. The observation of such increases in many cases is made at interim sacrifices performed during long-term exposure studies in animals. Benign tumors may eventually become malignant, and benign tumors themselves may pose serious health hazards.

Q.18. How should reproductive or developmental toxicity data be evaluated for possible TSCA §8(e) submission if maternal toxicity is also present?
A.18. Statistically or biologically significant increases in reproductive or developmental toxicity should be reported under TSCA §8(e) regardless of the level of maternal toxicity observed in the study. Data indicating maternal toxicity without accompanying developmental toxicity in such studies should also be considered for TSCA §8(e) reporting.

Q.19. What criteria should be used to determine which reproductive or developmental effects observed in animal tests are reportable under TSCA §8(e)? For example, should reversible developmental effects, such as reduced birth weight and/or incomplete ossification, trigger TSCA §8(e) reporting?
A.19. In addition to teratogenic effects, all adverse developmental and reproductive effects regardless of reversibility should be considered for reporting under TSCA §8(e). This includes any effect on the developing organism that is observed prenatally or postnatally, and any effect on the male or female reproductive system.

Q.20. When evaluating repeated dose toxicity studies, what criteria should be used to determine the reportability of adverse effects? For example, should increased or decreased organ weights in the absence of histopathological changes be reported to EPA under TSCA §8(e)?
A.20. Toxic effects observed during the conduct of repeated dose toxicity studies should be considered for TSCA §8(e) reporting. These effects include frank toxicity that is readily observable as well as adverse effects seen only as the result of gross and/or histopathological examination. Liver or kidney weight changes alone that are less than 10% of total body weight, except in developmental toxicity studies, are rarely in practice considered by EPA to be of biological significance and therefore would not be reportable under TSCA §8(e). Other organ weight changes should be evaluated on a case-by-case basis. As with acute toxicity studies, the degree of toxicity is important. The more serious (or significant) the observed effect, the less emphasis should be given to actual or potential exposure for TSCA §8(e) reporting, i.e., the most serious human health effects are reportable without considering exposure, which is presumed.

Q.21. What criteria constitute evidence of reportable neurotoxicity in animal studies? For example, are reversible effects such as narcosis or effects observed in the presence of marked systemic toxicity considered reportable?
A.21. Typically, cageside observations of neurotoxic effects in dying animals in acute toxicity studies are not considered by EPA to be reportable under TSCA §8(e). If neurotoxic effects are observed along with other effects that are reportable, inclusion of the neurotoxicity data should be considered for a more complete report of the effects observed. In short or long-term toxicity studies in which serious neurotoxic signs and symptoms (e.g., convulsions, sleep induction, motor dysfunction, narcosis, behavioral dysfunction) are seen in non-moribund animals, such effects should be considered for reporting under TSCA §8(e).

Q.22. What criteria should be used in determining if the results of acute toxicity studies in animals constitute information that reasonably supports a conclusion of substantial risk?
A.22. Criteria used to determine TSCA §8(e) reporting in the case of acute toxicity findings in animals depends on the nature of the effects observed and the dose at which the effects occurred. For example, data showing a tested chemical to be extremely toxic (e.g., lethality at very low doses) by inhalation, dermal or oral administration should be reported. On the other hand, the need to report data indicating that a chemical has a moderate degree of acute toxicity depends on the degree of actual or potential exposure to the tested chemical. Information showing a chemical to be slightly or minimally toxic on an acute basis is not typically considered to be reportable. The following table developed from the 1991 TSCA Section 8(e) Reporting Guidance and 1996 EPA hazard ranking system for TSCA §8(e) triage evaluation can be used as a guide to TSCA §8(e) reportability of acute animal toxicity:

Factors to Consider in Determining TSCA §8(e) Reportability of Acute Toxicity Data

Oral LD50	Dermal LD50	Inhalation LC50 (4-hr.)	Consider Exposure?
≤50 mg/kg	≤200 mg/kg	≤200 ppm (≤2 mg/l)	No - Highly Toxic
>50-500 mg/kg	>200-2,000 mg/kg	>200-5,000 ppm	Yes - Moderately Toxic
>500 mg/kg	>2,000 mg/kg	>5,000 ppm (>50mg/l)	Not Reportable

(LD50 = lethal dose to 50% of animals; LC50 = lethal concentration to 50% of animals)

In addition to lethality data, other adverse effects (e.g., neurotoxicity, sensitization, or skin or eye irritation not predicted by a chemical's physicochemical properties) observed in acute toxicity studies should be considered for reporting under TSCA §8(e).

Q.23. How can reportable information under TSCA §8(e) be distinguished from routine tests, such as LD50s and range-finding tests?
A.23. The June 3, 2003, Republication of the TSCA Section 8(e) Reporting Guidance discusses the types of effects that should be reported when unknown to the EPA Administrator. Although many routine tests are based on a knowledge of toxicity associated with a chemical, previously unknown effects can occur during such tests and may be reportable if the information meets the criteria described in Part V. of the 2003 Reporting Guidance. The most serious human health effects include any pattern of effects or evidence that reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation, including the loss of a normal bodily function resulting in relatively serious impairment of normal activities. For these effects, exposure is presumed. For other human health effects, the level of exposure or potential exposure should be used to determine TSCA §8(e) reportability. Routine LD50 and range-finding tests should be considered for TSCA §8(e) reporting if the data in question indicate adverse effects at dose levels below those previously reported.

Q.24. What adverse effects in environmental species are reportable under TSCA §8(e)?
A.24. Ecologically significant changes in species' interrelationships should be reported, as well as any non-trivial adverse effect unknown to the Administrator and associated with a chemical known to have bioaccumulated to a pronounced degree or to have the potential for widespread environmental exposure. The following table developed from the 1996 EPA hazard ranking system for TSCA §8(e) triage evaluation can be used as a guide to TSCA §8(e) reportability of acute and chronic toxicity to aquatic organisms. No comparable criteria are available for other environmental species and therefore adverse effects in non-aquatic organisms should be evaluated on a case-by-case basis.

Factors to Consider in Determining TSCA §8(e) Reportability of Aquatic Toxicity Data

Concern Level	Acute LC50 or EC50 (mg/L)	Chronic EC50 (mg/L)	Consider Exposure?
High	<1	<0.1	Yes
Moderate	1-100	0.1-10	Yes
Low	>100	>10	Not Reportable
Low	No effects at saturation	No effects at saturation	Not Reportable

(LC50 = lethal concentration in 50% of organisms)
(EC50 = effective concentration in 50% of organisms, e.g., reproductive performance or loss of mobility)

Health and Safety

Q.25. Are studies or reports showing absorption from manufactured products or articles of a chemical known to be capable of causing serious health effects potentially reportable under TSCA section 8(e)? For example, are studies or reports showing absorption of lead following oral or dermal exposure to a particular type of article for which it was not previously known that such absorption could occur potentially reportable under TSCA 8(e) ?
A.25. Yes – The discovery of previously unknown and significant human exposure to a chemical, when combined with knowledge that the subject chemical is recognized or suspected as being capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity), provides a sufficient basis to require the reporting of the new-found exposure data to EPA under section 8(e).

Q.26. Is the discovery of a hazardous or toxic constituent in a product reportable under TSCA section 8(e)?
A.26. Reporting of the presence of a hazardous or toxic constituent that was previously unknown to be contained in a product, including manufactured articles, should occur under TSCA section 8(e) where data shows that widespread or significant exposure to the toxic component has occurred or is substantially likely to occur, and such exposure presents a substantial risk of injury to health or the environment. Persons subject to TSCA 8(e) reporting should consider the toxicity of the constituent, the constituent's concentration in the product, and whether significant exposure to the toxic component has occurred or is likely to occur at any stage in the product's lifecycle from production through disposal. In cases of extremely toxic chemical substances in products in commerce, exposure may generally be presumed.

Environmental Contamination

Q.27. What is meant by widespread and previously unsuspected distribution in environmental media?
A.27. "Widespread distribution" means extensive. Persons with a possible TSCA §8(e) reporting obligation should consider amount, extent and patterns of contamination in determining if distribution is extensive enough to be considered widespread. For example, a chemical spill involving thousands of pounds of a toxic chemical is TSCA §8(e) reportable if it migrates to groundwater where there is a reasonable possibility of exposure to humans or environmental species through drinking water or agriculture. But a smaller chemical release that was cleaned up and contained before any substantial distribution to the environment occurred may not be TSCA §8(e) reportable. "Previously unsuspected" is not only unknown, but considered unlikely based on previously available information. "Environmental media" are soil, sediment, surface and ground water, air (including workplace and other indoor air) and, by extension, commercial products containing toxic chemical contaminant(s).

Q.28. In many cases, regulations, orders, or permit provisions require monitoring (e.g., National Pollutant Discharge Elimination System [NPDES] requirements) and contain triggers for reporting or performing an action when monitoring data indicate environmental releases in excess of permit limits. Are monitoring data that EPA or a state agency by rule, order, or permit under the authority of a federal statute has required to be collected but not reported because permit levels were not exceeded, ever subject to TSCA §8(e) reporting?
A.28. Regulations, orders and permits with threshold triggers for reporting are among the benchmark levels that EPA instructs persons to consider. When data are required to be collected but reporting is not triggered by the levels found because they are below regulatory threshold levels, then there is a presumption that reporting such information under TSCA §8(e) is not warranted. However, there may be circumstances where additional data indicate otherwise (e.g., unexpected persistence, bioaccumulation, widespread contamination or toxicity information not considered in setting a permit or an order that would be likely to lower the reporting level under that permit). Reporting under TSCA §8(e) should be considered in those cases.

Q.29. The Department of Transportation (DOT) has set forth specific reporting criteria for pipeline releases (e.g., 49 CFR parts 191-195). Releases at or above the specified criteria are reported to the National Response Center, are "known to the Administrator" and therefore not reportable under TSCA §8(e). Are pipeline releases regulated by DOT that are below DOT criteria ever reportable under TSCA §8(e)?
A.29. DOT has conducted extensive rulemakings to establish reporting requirements for significant environmental releases. Releases below these criteria are presumed not to present a substantial risk of injury and are not reportable under TSCA §8(e). However, there may be circumstances where additional data indicate otherwise (e.g., unexpected persistence, bioaccumulation, widespread contamination or toxicity information not considered in the reporting criteria that would be likely to alter the specific reporting criteria for pipeline releases). Reporting under TSCA §8(e) should be considered when a person with a TSCA §8(e) reporting responsibility possesses such additional data.

Q.30. A substance is known to be toxic to fish. The substance is detected in soil, where fish are not present. Does TSCA §8(e) reporting need to be considered?
A.30. Yes. Although it is well recognized that fish are not exposed to a substance in soil, fish could be exposed to the substance from soil runoff or groundwater migration to surface waters inhabited by fish. Persons subject to TSCA §8(e) reporting should consider whether distribution of the substance in the environment is widespread and whether there is a substantial likelihood of exposure to fish through migration of the substance in the environment.

Q.31. For non-human organisms, what factors should be considered for TSCA §8(e) reporting under Part V. (b) of EPA's June 3, 2003, TSCA Section 8(e) Reporting Guidance?
A.31. Any of the following factors, coupled with significant levels of exposure or potential exposure (based on production levels, persistence, uses, means of disposal or other pertinent factors), should be considered for TSCA §8(e) reporting involving environmental species:
Information on widespread and previously unsuspected distribution in environmental media of a chemical substance or mixture, when both of the following conditions are met:
Chemical substance or mixture is known to cause serious adverse effects in non-human organisms and
Widespread or significant exposure to non-human organisms has occurred or there is a substantial likelihood that such exposure will occur.
Pronounced bioaccumulation unknown to the EPA Administrator when coupled with the potential for widespread exposure and any non-trivial adverse effect.
Any non-trivial adverse effect unknown to the EPA Administrator associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in the environment.
Ecologically significant changes in species' interrelationships, such as excessive stimulation of algae or other primary producers.
Ready transformation or biodegradation to a chemical having unacceptable risks (toxicity and exposure) to non-human organisms.
Emergency incidents of environmental contamination that, because of the pattern, extent and amount of contamination, seriously threatens non-human organisms with large-scale or ecologically significant population destruction.

Q.32. Does the discovery of environmental contamination by known toxic environmental contaminants, such as dioxins, polychlorinated biphenyls (PCBs), perfluorinated chemicals or methyl t-butyl ether, need to be considered for reporting under TSCA §8(e)?
A.32. Yes. Although the presence of toxic chemicals in environmental media may be well known, one of the purposes of TSCA §8(e) reporting is to identify previously unsuspected environmental contamination at different sites. While new effects data can be corroborative of existing data, environmental contamination data can be site-specific and do not necessarily corroborate other site-specific data. However, to the extent that the discovery of environmental contamination would be reported fully and in a timely manner to Federal or state authorities under various programs such as the Underground Storage Tank (UST) and Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) programs, and various local and state site remediation programs, TSCA §8(e) reporting would not be required.

Q.33. Contamination is discovered within the boundaries of an active or inactive industrial facility controlled by a company potentially subject to TSCA §8(e) reporting. The evidence shows that the contamination has NOT migrated off-site. Does the contamination represent "widespread distribution in environmental media of a chemical substance or mixture" under Section V. (b)(1) of EPA's TSCA §8(e) guidance?
A.33. Contamination that occurs within the boundaries of an industrial facility may or may not become sufficiently widespread to be considered for TSCA §8(e) reporting. Factors such as contamination of groundwater or migration through air to surrounding populations should be considered in deciding whether the contamination is reportable under TSCA §8(e).

Q.34. Evidence of contamination is obtained at an industrial site with an ongoing company-sponsored program for containing and managing contaminated soil or groundwater. Can ongoing remediation activities be considered in determining whether the contamination is "widespread"?
A.34. Containment, management and remediation are more appropriately risk management considerations than criteria for TSCA §8(e) reporting. Consideration of widespread environmental contamination should be based on the amount, extent and pattern of contamination. These factors, coupled with information on whether or not widespread or significant exposures to humans or environmental species has occurred or is likely to occur, along with known serious toxic effects, should be the basis for determining TSCA §8(e) reportability.

Q.35. A manufacturer obtains evidence of contamination, and then promptly implements measures to contain the contamination. If the contamination is controlled prior to the deadline for reporting under TSCA §8(e), is the information reportable?
A.35. The reporting deadline is NOT a factor to consider in determining if information reasonably supports the conclusion of a substantial risk. If the contamination was controlled such that it never became widespread, the manufacturer should consider whether severe toxic effects were observed as a result of the contamination. If such effects were not observed, TSCA §8(e) reporting would not be required. However, if the contamination becomes widespread or severe toxic effects are observed, reporting should be considered.

Reporting of Modeling and Risk Assessment Studies

Q.36. Companies often perform air dispersion, groundwater migration or other types of modeling to estimate the magnitude and extent of a chemical's presence in environmental media following its release from a manufacturing, processing, or disposal facility. Under what circumstances are the results of such modeling subject to TSCA §8(e) reporting?
A.36. Modeling information alone is not reportable under TSCA §8(e), but it is often useful in interpreting measured data obtained from monitoring or other sources to determine TSCA §8(e) reportability. For example, reporting of non-emergency situations of environmental contamination may be warranted where modeling results reliably support available information that the contamination involves widespread and previously unsuspected distribution in the environment of a chemical known to cause serious adverse effects to humans or non-human organisms at projected exposure levels.

Q.37. Should risk assessments conducted under California's Proposition 65 and Hot Spots Law (the Safe Drinking Water and Toxic Enforcement Act of 1986 and the Air Toxics Hot Spots Information and Assessment Act of 1987) be considered for TSCA §8(e) reporting?
A.37. In cases where the risk assessment relies on actual data showing that widespread and previously unsuspected environmental distribution and exposure to a chemical known to cause serious adverse effects has occurred or is substantially likely to occur, submission of the exposure data underlying the assessment should be considered for TSCA §8(e) reporting. However, to the extent that Proposition 65 and Hot Spots reporting triggers are based on conservative safety factors and exposure scenarios, the applicability of such requirements may not necessarily coincide with TSCA §8(e) reporting criteria. If exposure data underlying the assessment are reported, the assessment itself may be submitted as supplementary information, but its submission is not required.

Q.38. Would industrial hygiene assessments need to be considered for TSCA §8(e) reporting?
A.38. Typically no. Such assessments are often conducted in situations where potential exposure to the chemical has already been identified. For example, contamination of workplace air or surfaces by substances known to the manufacturer and EPA, such as Occupational Safety and Health Administration (OSHA) regulated substances, would not need to be examined for §8(e) reporting under Part V. (b)(1) of the TSCA Section 8(e) Reporting Guidance because they are not "previously unsuspected." However, information should be considered for reporting if it reasonably supports a conclusion of substantial risk (combination of toxicity and exposure) that was previously unknown. In order for workplace situation to be reportable under TSCA §8(e), it would need to be previously unsuspected and involve serious toxic effects. Also, a sudden release of a large quantity of an OSHA regulated substance may need to be considered for TSCA §8(e) reporting as an emergency incident of contamination, depending on the quantity and toxic properties of the substance.