



Reporting Substantial Risks Under TSCA 8(e)

12.17.2018

The Toxic Substance Control Act (TSCA) contains a variety of reporting and recordkeeping requirements for companies that manufacture, import, process, or distribute into commerce a chemical substance or mixture. This article answers questions concerning reporting “substantial risks” under Section 8(e) of TSCA.

QUESTION 1: Who is covered by TSCA 8(e) reporting?

ANSWER: TSCA requires “any person who manufactures (including imports), processes, or distributes in commerce a chemical substance or mixture” to file a Section 8(e) Report if the processor (1) “obtains information,” (2) which “reasonably supports” a conclusion that, (3) the chemical substance or mixture “presents a substantial risk of injury to health or the environment.”

Important limitations on the reporting requirement are established by EPA guidance, including the following:

1. No report is necessary where EPA has been “adequately informed of such information”;
2. Persons are subject to reporting only to the extent they are engaged in manufacturing (importing), processing, or distributing chemicals into commerce -- labor unions, trade associations, contract testing labs, and those no longer engaged in covered actions are exempt.
3. There are no exemptions, however, for small businesses, production or import volumes, or levels of commercial activity.

QUESTION 2: What is “substantial risk” information?

ANSWER: In sum, substantial risk information is simply any “reasonable” information about an injury or risk to human health or the environment. The information need not, and typically does not, establish conclusively that a substantive risk exists. According to EPA, “[i]n deciding whether information is “substantial risk” information, one must consider (1) the seriousness of the adverse effect, and (2) the... probability of the effect’s occurrence.” The greater the seriousness of risk or effects, the less probability

is required.

QUESTION 3: When is a company deemed to have “obtained information” sufficient to trigger Section 8(e) reports?

ANSWER: Section 8(e) reports relate to adverse effects in “possession of the person” or about which the person has knowledge. Examples include when:

- Officers or employees “capable of appreciating the significance of the information” receive it, or
- Training, job function, or experience causes one to “reasonably [be] expected to know” of the risks.

Companies are not compelled to actively search for substantial risks, but “negligence or intentional avoidance of information” may lead to liability.

QUESTION 4: What information is considered to already be within EPA knowledge and therefore not reportable?

ANSWER: TSCA Section 8(e) excludes from reporting any substantial risk information about which EPA has been “adequately informed.” EPA guidance suggests information within the following sources is excluded from reporting: an EPA study or report; open scientific literature; submissions required to be made to EPA by statute; publication/reports of other federal agencies; and well-established “scientific journals.” However, mandatory reports filed by your company with another agency do not qualify for the exclusion.

QUESTION 5: When are Section 8(e) reports due?

ANSWER: Substantial risks must be reported within 15 working days after obtaining the information.

It seems clear Section 8(e) reporting is not a routine occurrence. However, learning new risks or injuries from chemical substances and mixtures at your plant certainly may trigger new reporting requirements.

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