

4. Eliminate the need to follow up an emergency release notification under Part V.(c) with a written report.

5. Clarify standards for claiming CBI in section 8(e) notices.

6. Correct the address under Part IX. of the 1978 Policy Statement.

B. Summary of Public Comments on the 1993 and 1995 Proposed Revisions and EPA's Responses

In addition to the brief summaries of public comments and Agency responses presented in this **Federal Register** document, EPA has prepared a "response to comments" document that addresses in greater detail the significant comments it received on the proposed changes. The public version of the "response to comments" document, which does not contain any CBI information, is publicly available in the docket described in Unit I.B.1 of this document.

1. *Comments on the 1993 proposed changes.* EPA received comments from 49 companies and industry associations in response to the 1993 **Federal Register** document. Commenters suggested that EPA's proposed plan for environmental reporting lacked criteria that were sufficiently clear to enable companies to separate "routine" releases, which need not be reported, from the "extraordinary" releases, which were to be reported under section 8(e). Commenters stated that EPA should provide clearer criteria for determining when a situation presents a "substantial risk," and should provide as many "bright lines" as possible to indicate what would and would not be reportable under section 8(e). Specifically, commenters:

- Questioned EPA's interpretation of when contamination would be "widespread."
- Stated that only a contaminant's "known" toxicity should be considered.
- Stated that for contamination to be reportable, it must be "previously unsuspected" contamination.
- Stated that the contamination must result in actual or high probability of significant exposure to humans or non-human organisms.
- Stated that any contamination to be reported under section 8(e) must "present" a substantial risk rather than only a speculative "may present."
- Proposed that EPA establish a decision tree that companies could follow to determine whether to report incidents involving environmental contamination under section 8(e). Commenters stated that if companies had sequential criteria, they would be in a much better position to comply with

the reporting requirements of section 8(e).

- Supported the change to the section 8(e) notice reporting period from 15 working days to 30 calendar days.

The bulk of the remaining comments concerned circumstances under which companies need not report information to EPA. EPA had proposed to exempt from reporting under TSCA section 8(e) information companies were required to report under other EPA authorities (including those delegated to the States). However, the exemption would only apply if the information was submitted under the other authorities within 30 days of obtaining the information. Commenters believed that this would offer little relief because many of the other authorities have reporting periods longer than 30 days. The companies would either have to accelerate their reporting under authorities other than TSCA section 8(e) or submit two reports, one within 30 days under section 8(e) and another within the time frame of the other requirement. The commenters suggested allowing a longer time frame, i.e., 90 days or longer, for that information submitted under authorities other than TSCA section 8(e).

Commenters also suggested expanding the "other authorities" exemption to include reporting under all Federal environmental statutes as well as State laws and regulations, especially when a site is undergoing remediation for contamination with hazardous waste and any environmental or health threats associated with those contaminants are being addressed in the course of the remediation.

Finally, EPA received comments on the relationship of the revised guidance to phase 2 of the CAP. The sentiment expressed by all those who commented on this issue was that, given the limited guidance in the 1978 Policy Statement, EPA's suspension of the guidance section on environmental contamination, and the likelihood that EPA's final guidance would be essentially "new," the final guidance should only be enforced prospectively. Consequently, companies should not be subject to any liability for past failures to report under the criteria of the "new" guidance.

2. *EPA's response to comments on the 1993 proposed changes; the 1995 proposed draft guidance.* In response to the comments received on the 1993 proposed changes to the 1978 guidance, on March 20, 1995, EPA issued revised proposed guidance to address the commenters' concerns.

First, in the 1995 notice, EPA proposed clarifications to the situations

involving environmental contamination which EPA believes would need to be reported. Language suggested in comments to the 1993 notice was adopted, specifying that the contamination must be "previously unsuspected," that "exposure" has occurred or there is a substantial likelihood that it will occur, and that the chemical(s) in question is "known" to cause serious adverse effects. EPA stated that information on those effects could be obtained from several sources:

- Databases available to the public (online or in paper versions), such as the National Library of Medicine (NLM) databases (Toxline, Medline, Hazardous Substances Data Bank, etc.), National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS), EPA's Aquatic Toxicity Information Retrieval database (AQUIRE) (Now the Ecotoxicology (ECOTOX) database) www.epa.gov/ecotox/.
- Reports to EPA or other government agencies.
- Unpublished data known to the person or entity subject to reporting.

As regards the issue of what is meant by "known" to cause serious adverse effects, EPA did not mean that the effects must be conclusively shown and did not intend a higher standard of certainty than for the "effects" reporting part of the 1978 Policy Statement. In that notice, EPA stated that all that is needed for an effect to be "known" is that the information reasonably supports that the chemical can cause the effect(s) of concern. This issue is addressed in the 1978 Policy Statement in EPA's response to comments that questioned the use of "may suggest" language regarding information obtained and the reporting of substantial risk information (see Supplementary Information paragraph (3) of the 1978 Policy Statement).

In addition, EPA agreed to allow the use of "benchmark levels" to help determine if the information should be reported. EPA has established benchmark levels for various substances. Benchmark levels are concentrations that either trigger a regulatory response, or concentrations above which a substance is presumed to present a risk to health and/or the environment. For instance, the Agency has developed Reference Doses (RfD's) for numerous substances under its Integrated Risk Information System (IRIS). Reference doses establish a level of exposure where no adverse effects would be expected to be manifested. Thus, if a person found groundwater contaminated with a chemical at a level that did not exceed the RfD for that