



January 31, 2008

Jim Willis  
Director, Chemical Control Division  
Office of Pollution Prevention and Toxics  
US EPA Headquarters, Ariel Rios Building  
1200 Pennsylvania Ave., NW,  
Mailcode 7405 M  
Washington, DC 20460

**Re: TSCA § 8(e) and Biomonitoring Guidance**

Dear Mr. Willis:

In July 2007, representatives of the American Chemistry Council met with you and your staff to discuss ACC's recommendations for EPA to develop clarifying guidance on the application of TSCA 8(e)'s reporting requirements to biomonitoring information. A discussion document we provided the Agency in May 2007 served as the basis of our recommendations. At the time, you expressed interest in the topic, but given the priority of the issue to the Agency you predicted EPA would be unlikely to develop full guidance on it; that Q & As were probably the best the Agency could do here. You requested our thoughts on key topics for Q & As, which we submitted to you by email. Since then, we've heard no more from the Agency on this subject.

Based on ACC's concerns about the continuing lack of guidance in this area, we have prepared some draft Q & As on these same topics for your consideration (attached). These are based on the longer discussion document we provided you last year (also attached). We are hopeful that these draft Q & As will help the Agency move more swiftly to provide clarifying guidance on this topic.

I will contact you shortly to discuss this important topic further. In the meantime, if you have any questions, please call me at: 703-741-5159.

Sincerely,

A handwritten signature in black ink that reads "Sarah H. Brozena".

Sarah H. Brozena  
Senior Director  
Regulatory and Technical Affairs

## **Proposed Questions and Answers on TSCA Section 8(e) and Biomonitoring**

EPA's current Q&A on biomonitoring reads:

**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>.

That Q&A would be replaced by the following:

Q1: What are the criteria for deciding whether biomonitoring results in humans should be reported under Section 8(e)?

A1. EPA published a revised TSCA Section 8(e) Policy Statement and Guidance in 2003, available at <http://www.epa.gov/opptintr/tsca8e/pubs/rguide03.htm>. Biomonitoring results that relate internal exposure levels to adverse human health effects should be evaluated under Part V(a) of that Policy Statement. Biomonitoring results that provide only exposure information should be assessed under Part V(b)(1), relating to non-emergency situations of chemical contamination involving humans and/or the environment. It reads in part:

Information that pertains to widespread and previously unsuspected distribution in environmental media of a chemical substance or mixture known to cause serious adverse effects, when coupled with information that widespread or significant exposure to humans or non-human organisms has occurred or that there is a substantial likelihood that such exposure will occur, is subject to reporting. The mere presence of a chemical in an environmental media, absent the additional information noted above, would not trigger reporting under section 8(e).

Q2: Should occupational biomonitoring results be considered for reporting under Section 8(e)?

- A2: In many cases occupational exposure to a chemical for which workplace biomonitoring is being conducted would be known, and therefore not “previously unsuspected”. Biomonitoring results in worker populations would not indicate “widespread or significant” exposure unless those results reach extraordinary levels (e.g., substantially above established standards such as OSHA levels for worker removal or substantially above voluntary guidelines such as ACGIH Biological Exposure Guidelines). Moderately elevated biomonitoring results for chemicals to which occupational exposure is known would not be reportable.
- Q3: Should biomonitoring results in a sampling of the general population be considered for reporting under Section 8(e)?
- A3: Yes. Such results should be considered for reporting because the presence and levels may be “previously unsuspected”. In evaluating such results, use a sliding scale, taking into account factors such as the following, among others:
- (1) Is the chemical detected known to cause serious or adverse effects under Section 8(e) and EPA guidance? (If not, the information is not reportable. If so, consider the following factors, among others.)
  - (2) To what extent do the results exceed background levels (e.g., those reported in the Centers for Disease Control and Prevention’s “National Report on Human Exposures to Environmental Chemicals”) or health-based reference levels? (The more the results exceed background levels, the more likely they would be considered reportable. Mere detection of the chemical is not enough to trigger reporting.)
  - (3) Do the results suggest an exposure source or pathway (e.g., exposure through drinking water or proximity to an area where the chemical is known to be present), or an extended time needed to eliminate the chemical from the body (e.g., elevated levels in persons removed from exposure)?
  - (4) Do the results indicate that the chemical can cross the placental barrier or appear in breast milk?
- Q4: What are some factors that would make biomonitoring results not be reportable under Section 8(e)?
- A4: The following factors would mean that the biomonitoring results would generally not be reportable:
- (1) Detection of a chemical at or near background levels. (Such results would not be “significant”.)
  - (2) Biomonitoring results that do not meet minimum professional standards for data recording, methodology, etc. (Such results would not be reliable.)
  - (3) Biomonitoring results in persons located outside the United States. (Such results should only be considered for reporting if they provide information in addition to exposure, e.g., information relating internal exposure levels to

adverse human health effects, information that the chemical can pass through the placenta or into breast milk, or information that an extended time is needed to eliminate the chemical from the body.)

- (4) Biomonitoring results reported on the Internet or by the media. (Such results would be known to the Administrator).