
TSCA Section 8(e) and Human Biomonitoring: A Cautionary Tale

Mark Duvall
Managing Counsel
The Dow Chemical Company

Introduction

- TSCA Section 8(e) is the oldest and least understood aspect of TSCA
- It covers effects AND exposure
- In 2005 a watershed event in the history of Section 8(e) occurred whose implications are still being worked out
 - DuPont settled its Section 8(e) biomonitoring case for the largest administrative penalty in history
 - The case produced industry consternation but little EPA guidance
- Companies today remain vulnerable for documents in their files that could cost them millions of dollars
- This potential liability grows over time

Overview

- Summarizes the Section 8(e) basics
- Reviews the DuPont Section 8(e) enforcement case (as presented in public documents)
- Reports on ACC's actions to request guidance on reportability of human biomonitoring results under Section 8(e)
- Makes recommendations

Text

- “Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such knowledge unless such person has actual knowledge that the Administrator has been adequately informed of such information.”

Early Guidance

- Original guidance: 43 Fed. Reg. 11110 (Mar. 16, 1978)
- 1977-1990: EPA published summaries of Section 8(e) submissions with commentary
- Companies agonized about whether to submit and “disparage” chemicals
- Jan. 1977 – Sept. 1990: 1,084 submissions

History

- 1989: Monsanto dialogue with EPA
 - “Substantial risk” as applied to toxicology data means “hazard information”, not “risk assessment”
 - Generally low threshold for reportability
 - Revolutionized industry’s understanding of Section 8(e)

History

- 1991-92: Compliance Audit Program (CAP)
 - Companies could submit potentially reportable information to EPA subject to limited penalties with a penalty cap of \$1 million
 - EPA provided new guidance: TSCA Section 8(e) Reporting Guide (June 1991)
 - Several companies reached the cap

History

- Following the CAP, EPA received many more submissions than before
 - ❑ Companies no longer agonized over decisions to submit information
 - ❑ EPA stopped publishing summaries of submissions – too many
 - ❑ By end of 2000: 14,855 submissions
 - ❑ Currently over 17,000 submissions

Current Guidance

- 2003: Revision to 1978 guidance
 - 68 Fed. Reg. 33129 (June 3, 2003)
 - Corrected, 70 Fed. Reg. 2162 (Jan. 12, 2005)
 - Most of the 1978 guidance carried over
 - Expanded exemptions
 - Q&As, Response to Comments helpful also

Current Guidance

- Part V(a): Human health effects information
 - Serious adverse health effects: “Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated” or pattern or evidence that “reasonably supports the conclusion that” a chemical can produce such effects
 - Mostly derived from animal studies
 - Some objective guidance
 - Hazard-based

Current Guidance

- Part (V)(b)(1): Information on non-emergency contamination (exposure) in humans or the environment
- Part (V)(b)(2)-(5): Environmental effects information
- Part (V)(c): Emergency incidents of environmental contamination (see NRC)
- Part VII: Exemptions (“known to the Administrator”)

Exposure Information

- Part V(b)(1): “Non-emergency situations of chemical contamination involving humans and/or the environment: 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).”

Exposure Information

- Part (V)(b)(1) guidance from EPA:
 - “Known to cause serious adverse effects” – same standard as for Part V(a) – not conclusive
 - Exposure at or below an MCL, RfD, RfC, or TCL is not reportable (exposure above these must be “significant” or “widespread”)
 - Sliding scale of potential exposure and potential effects
 - Occupational exposure is often not “previously unsuspected”
 - No health effects required for reporting (chemical is known to cause adverse health effects)
 - Information about a site outside the U.S. is not reportable unless contamination could come to U.S.

Human Biomonitoring Information

- 1980 - 1997: Few submissions mentioning human biomonitoring results
- 1998 - 2002: 3M submitted large numbers of worker and community biomonitoring results for fluorinated chemicals
- 2003: ACC Brominated Flame Retardants Panel submitted information on BFRs in breast milk in Norway

DuPont Litigation: Counts

- First Section 8(e) enforcement action relating to biomonitoring (human exposure) information
- July 2004: 3-count complaint issued
 - **Count 1:** Failure to submit under Section 8(e) 1981 one-page document on fluorinated chemical levels measured in the babies or in umbilical cord blood of babies of exposed employees (showed migration)
 - **Count 2:** Groundwater information under Section 8(e)
 - **Count 3:** RCRA

DuPont Litigation: Counts

- December 2004 – amended complaint
 - **Count 4:** Failure to submit fluorinated chemical blood levels in 12 community residents
- December 2005 – settlement agreement added:
 - **Count 5:** Failure to submit fluorinated chemical blood levels in 10 additional community residents
 - **Counts 6-8:** Tox studies

DuPont Litigation: Proposed Penalties

- None listed in the complaints
- EPA calculated potential penalties based on \$25,000+/day for nearly 20 years:
- Count 1: \$183,837,500
 - Codex Leicester: \$30.8 million
- Count 4: \$42,250
- Counts 5-8: \$4,500,000

DuPont Litigation: Settlement

- Counts 1-4 settled for \$10 million + \$5 million SEP
- Counts 5-8 settled for \$250,000 + \$1.25 million SEP
- \$10.25 million is largest administrative penalty under any EPA statute
- More than 10x largest previous Section 8(e) penalty (CAP)
- More than 40% larger than next largest administrative penalty in EPA history
- Higher penalties have been assessed by courts

DuPont Litigation: Arguments

- DuPont Count 1 arguments
 - “Biomonitoring data alone is not substantial risk information.”
 - “The presence of a chemical, in the absence of an adverse effect, does not trigger reporting requirements.”
 - DuPont had submitted under Section 8(e) an animal study showing fluorinated chemical crossed placenta
 - EPA scientists and others have long known that “virtually all chemicals the size of [fluorinated chemical] will pass through the human placenta.”
- EPA Count 1 arguments
 - “EPA considers the data to be highly significant because the Agency did not previously have any data from humans showing movement of [fluorinated chemical] from mother to fetus, only data from lab animals.”

DuPont Litigation: Arguments

- DuPont Count 4 arguments
 - Community results were orders of magnitude below worker levels not shown to cause adverse effects
 - EPA was on notice of worker results
- EPA Count 4 arguments
 - 12 community residents results were the first community results EPA had seen for these chemicals
 - The results were “particularly useful because they represent an attempt to associate body burden in the general population with a specific exposure pathway and a source of exposure.”

DuPont Litigation: Implications

- Contributing factors:
 - Involvement of controversial chemicals
 - Involvement of private litigation and NGO
 - Prenatal exposure
 - Community exposure
- Availability of rational arguments for non-submission may be insufficient to deter EPA once engaged
- Ambiguous EPA guidance
 - No clear resolution of DuPont arguments
 - No clear EPA guidance on biomonitoring or commitment to provide such guidance
 - Individual companies must develop their own guidance until EPA is more forthcoming

DuPont Litigation: Subsequent Developments

- Increase in Section 8(e) submissions on fluorochemicals
- Few other submissions on other chemicals
 - No relevant biomonitoring results?
 - Concern for liability for previous non-submission?
 - Lack of clear EPA guidance?
 - Lack of industry engagement?

DuPont Litigation: Subsequent Developments

- Sept. 2006: EPA Section 8(e) FAQ
 - Q: 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: 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.

DuPont Litigation: Subsequent Developments

- Section 8(e) FAQ:
 - “Information that corroborates known exposure levels and other biological monitoring data recorded in the NHANES data base is not reportable.”
 - CDC’s “National Report on Human Exposure to Environmental Chemicals” is derived from NHANES
 - No reference to Part V(b)(1)’s criteria of “widespread and previously unsuspected”, etc.
 - Any exposure (biomonitoring) data for toxics is reportable unless “known to the Administrator” – potentially huge liability for companies, no other criteria for reporting

ACC Request for EPA Guidance

- Dec. 2006: ACC met with EPA to ask for better Section 8(e) biomonitoring guidance than the Q&A – no response
- May 2007: ACC sent EPA 29-page request for guidance
- July 2007: ACC met with EPA to discuss
- Feb. 2008: ACC sent EPA draft Q&As to replace EPA Q&A

ACC Request for EPA Guidance

- May 2007 request – suggested criteria:
 - Biomonitoring results that correlate occurrence of adverse effects with internal exposure levels (some 3M fluorinated chemical submissions)
 - Biomonitoring results indicating that a chemical known to cause adverse effects has a long residence time in the body (some 3M fluorinated chemical submissions)

ACC Request for EPA Guidance

- Occupational biomonitoring results
 - Generally not “previously unsuspected” because potential exposure is known (unless previously thought unexposed)
 - Generally not “significant or widespread” unless very high
 - E.g., well above ACGIH Biological Exposure Index or OSHA criteria for worker removal from exposure
 - Based on analogy to Part V(b)(1) statement that exposure below RfD, etc. is not “significant”

ACC Request for EPA Guidance

- Non-occupational biomonitoring results
 - EPA has indicated that for a chemical plant, off-site groundwater contamination is “previously unsuspected” even though not surprising
 - By analogy, elevated results in community residents near a chemical plant are likely to be “previously unsuspected” even if not surprising

ACC Request for EPA Guidance

- Non-occupational biomonitoring results
 - Whether exposure is “significant” or “widespread” depends on sliding scale of exposure potential and effects potential
 - CDC and EPA: Mere presence in the body does not mean health risk
 - Health-based reference values may be helpful for determining “significant”, but occupational values may not be appropriate (e.g., children, elderly)
 - NHANES established background levels for many chemicals – exposures at or somewhat above background are not “significant”

ACC Request for EPA Guidance

- Non-occupational biomonitoring results
 - Generally, only levels several times background should be considered “significant”
 - DuPont Count 4: Levels were up to 25x above background, although well below occupational levels
 - Unless the results suggest a particular exposure pathway or unique and identifiable source
 - DuPont Count 4: Community residents exposed through drinking water wells
 - Proximity to source of airborne emissions

ACC Request for EPA Guidance

- Biomonitoring results indicating a chemical known to cause serious adverse effects can cross the placenta or show up in breast milk
 - DuPont Count 1
 - Even though scientists would expect the chemical could cross the placenta (human data is “previously unsuspected” despite availability of animal data)

ACC Request for EPA Guidance

- Exemption for unreliable information
 - Minimum professional standards
 - Plausible link with the chemical in question
- Corroborative information
 - NHANES data or similar
 - Substantial similarity needed
- Results for persons outside U.S.
 - Analogy to contamination at sites outside U.S.
 - Unless new pathway or correlation to effects
 - Several foreign results have been reported

ACC Request for EPA Guidance

- Exemption for biomonitoring guidance on third party websites
 - Analogous to published information exclusion
 - NGOs often post mini biomonitoring studies
- Apply biomonitoring guidance prospectively
 - Part V(b)(1) 2003 environmental contamination guidance applied prospectively
 - Potential liability in light of absence of prior guidance

Subsequent Developments

- At July 2007 meeting, EPA indicated that it lacks administrative resources to develop and review internally major Section 8(e) guidance on biomonitoring – not a priority
- Q&As more likely to be issued (fewer administrative resources needed)
- ACC recently submitted to EPA 4 draft Q&As based on the request for guidance
- Awaiting EPA action

Recommendations

- EPA should act on the request for guidance or the draft Q&As
- Industry should not expect further EPA guidance soon (environmental contamination guidance took 12 years)
- Companies remain vulnerable to enforcement actions similar to DuPont
 - Involvement of private litigation, NGO activism, and/or strong EPA interest in chemical increase risk
- Companies should consider adopting internal criteria for submitting biomonitoring data until EPA gives guidance
 - ACC suggestions may be a basis for internal criteria