



May 24, 2007

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Re: TSCA § 8(e) and Biomonitoring Guidance

Dear Mr. Willis:

I want to thank you and your staff for participating in the December 18, 2006 meeting with American Chemistry Council (ACC) representatives to discuss EPA's guidance on reporting human biomonitoring information under Section 8(e) of TSCA. At the close of the meeting, ACC was asked to provide written comments on the topic. The attached memorandum responds to that request. It is intended to promote further dialogue. It provides:

- An analysis of the available EPA guidance on application of TSCA 8(e) to human biomonitoring data.
- A discussion of the need for additional guidance on the characteristics that can make human biomonitoring data 8(e) reportable
- Recommended criteria for reporting human biomonitoring information that EPA may want to propose as guidance.
- Recommended guidance for excluding certain human biomonitoring information from coverage by Section 8(e).
- A recommendation that EPA guidance on TSCA 8(e) and human biomonitoring information be applied prospectively.

After you and other EPA staff have had an opportunity to review this memorandum, I will contact you to schedule a meeting to discuss this important topic further.

Sincerely,

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

Sarah H. Brozena
Senior Director
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**APPLICATION OF TSCA SECTION 8(e)
“SUBSTANTIAL RISK” REPORTING
TO HUMAN BIOMONITORING DATA –
SITUATIONAL ANALYSIS AND
REQUEST FOR GUIDANCE**

Submitted to U.S. Environmental Protection Agency by:

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May 24, 2007

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EXECUTIVE SUMMARY

The American Chemistry Council (ACC) has prepared this discussion paper to address an important regulatory compliance issue: The application of the Toxic Substances Control Act (TSCA) Section 8(e) “substantial risk” reporting provision, 15 U.S.C. § 2607, to human biomonitoring information.

Biomonitoring is a scientific technique for assessing human exposures to natural and synthetic chemicals based on sampling and analysis of an individual's tissues and fluids for the chemical itself, a breakdown product of the chemical or some other valid indicator (biomarker) of the chemical exposure. While blood, urine, hair, breast milk and expelled air are most commonly measured, sampling may involve other tissues.

Biomonitoring indicates the amount of a natural or man-made chemical present in the body at one point in time, but does not inform us about how the chemical got into the body, how long it has been there, or whether it poses any health risk. Biomonitoring is not a new exposure assessment technique, but its use has been increasing in recent years by the federal and various state governments, industry and NGOs as analytical capabilities have become more efficient and economical.

EPA’s long-standing TSCA 8(e) guidance dating back to 1978 and reaffirmed in 2003 does not expressly address biomonitoring, but establishes criteria in Part (V)(b)(1) for assessing the reportability of “chemical contamination involving humans and/or the environment”. Many companies have been relying on these criteria -- which focus on magnitude of the actual or potential exposures to the chemical relative to its risk -- to determine the reportability of biomonitoring information.

In September of 2006, EPA posted on the “Frequently Asked Questions” portion of its TSCA webpage an FAQ that expressly addresses biomonitoring. This FAQ, when read literally and in isolation, departs significantly from EPA’s long-standing guidance by suggesting that all biomonitoring for chemicals “known to cause serious adverse effects” -- regardless of the results and context -- should trigger 8(e) reporting unless the “corroborative” exemption applies to the information.

The regulated community now faces a confusing compliance landscape. EPA’s highly publicized Section 8(e) enforcement action against DuPont involved biomonitoring in part, but was settled last year without explanation as to the rationale behind EPA’s allegations. This indeterminate resolution places the regulated community in a posture of having to assess 8(e) reportability based on the only part of EPA’s long-standing guidance which appears relevant to biomonitoring -- Part V(b)(1) -- and to grapple with an FAQ which departs from that guidance and is

otherwise incomplete. This compliance challenge will intensify as biomonitoring becomes more prevalent.

ACC urges EPA to address this situation as soon as possible by issuing for public comment supplemental, biomonitoring-focused guidance. In the spirit of cooperation, ACC offers its preliminary views in this discussion paper on an approach to such guidance.

First, ACC suggests this supplemental guidance should key off the existing Part V(b)(1) criteria, which limit 8(e) reporting of “chemical contamination involving humans and/or the environment” to chemicals “known to cause serious adverse effects” where the information indicates both (i) “previously unsuspected” and (ii) “widespread” or “significant” exposure to such a chemical.

Second, application of the “previously unsuspected” and “widespread” or “significant” criteria to biomonitoring on such a chemical should result in a distinction between occupational and non-occupational biomonitoring. In the occupational setting, only extraordinary exposures should qualify as “previously unsuspected”, and hence, most occupational biomonitoring should not trigger 8(e) reporting.

Third, as to non-occupational biomonitoring, the reporting decision should take into account various factors, including, among others, the risk profile of the chemical relative to the biomonitoring information; the properties of the chemical bearing on exposure duration, pathways and levels; and statistical significance.

In general, non-occupational biomonitoring levels at or near health-based reference values should not trigger reporting; nor should biomonitoring levels consistent with established background levels. Even levels modestly above such values also may not trigger reporting, depending on the factors identified in the paragraph above. Exceptions to this general principle should arise, however, where the biomonitoring levels relate to (or tend to demonstrate a nexus to) a unique and identifiable exposure source and/or exposure pathway. Examples of such information may include, but are not limited to, biomonitoring information (i) for persons with a known or reasonably suspected specific route of exposure to the chemical (*e.g.*, drinking water) or (ii) indicating the presence of the chemical in breast milk and/or in umbilical cord blood.

Finally, the reporting exemptions for unreliable and corroborative information should provide the basis for not reporting biomonitoring in certain circumstances. In particular, biomonitoring should not qualify as sufficiently “reliable” to trigger reporting where the information was generated through flawed techniques, was made available by a third party in a form insufficient to establish reliability or reflects an implausible result. Similarly, where biomonitoring demonstrates levels comparable to

information already reported or known to EPA for the same or a substantially similar population, then the “corroborative” exemption should preclude reporting.

ACC appreciates the opportunity to provide EPA with this discussion paper and looks forward to working with the Agency on supplemental 8(e) guidance to address biomonitoring.

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INTRODUCTION

The American Chemistry Council (ACC) has prepared this paper to foster discussion with the United States Environmental Protection Agency (EPA) as to the reporting of human biomonitoring information under Section 8(e) of the Toxic Substances Control Act (TSCA). Biomonitoring is a scientific technique for assessing human exposures to natural and synthetic chemicals based on sampling and analysis of an individual's tissues and fluids for the chemical itself, a breakdown product of the chemical or some other valid indicator (biomarker) of the chemical exposure. While blood, urine, hair, breast milk and expelled air are most commonly measured, sampling may involve other tissues.

Biomonitoring indicates the amount of a natural or man-made chemical present in the body at one point in time, but does not inform us about how the chemical got into the body, how long it has been there, or whether it poses any health risk. Biomonitoring is not a new exposure assessment technique, but its use has been increasing in recent years by the federal and various state governments, industry and NGOs as analytical capabilities have become more efficient and economical.

On December 18, 2006, ACC had the opportunity to meet with EPA to discuss an FAQ posted in September 2006 regarding the application of TSCA Section 8(e) to biomonitoring. At the meeting, ACC was asked to provide additional explanation as to its view that this FAQ does not provide sufficient guidance. Our key concerns and suggestions follow below in three sections:

- ⇒ *Section I* addresses EPA's long-standing Part (V)(b)(1) guidance for assessing the reportability of "chemical contamination involving humans and/or the environment" and how the FAQ departs from this guidance.
- ⇒ *Section II* addresses the confusing current compliance situation in the aftermath of the highly publicized DuPont enforcement action that involved biomonitoring information in part and how this situation has been compounded by the FAQ and can be rectified only by supplemental, biomonitoring-focused guidance.
- ⇒ *Section III* addresses ACC's recommended approach for keying off EPA's long-standing Part (V)(b)(1) guidance and how to apply the "previously unsuspected" and "widespread" or "significant" exposure criteria in that guidance to biomonitoring information on chemicals "known to cause serious adverse effects".

DISCUSSION AND ANALYSIS

I. CRITIQUE OF EPA GUIDANCE ON APPLICATION OF SECTION 8(E) “SUBSTANTIAL RISK” REPORTING TO BIOMONITORING DATA

A. The September 2006 FAQ

The December 18th meeting arose because EPA had recently published the following FAQ on the application of Section 8(e) to human biomonitoring information:¹

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>.

At the meeting, the ACC representatives raised several concerns about the FAQ.

First, the FAQ does not match well with the criteria in Part V(b)(1) of EPA’s long-standing 8(e) guidance for “non-emergency situations of chemical contamination involving humans and/or the environment”² These criteria direct companies to assess the reportability of information regarding such contamination based on the magnitude of the actual or potential exposures to the chemical stemming from such contamination and to evaluate magnitude on a qualitative basis using a “sliding scale”

¹ The FAQ, part of the September 2006 Section 8(e) FAQs, is available at <http://www.epa.gov/oppt/tsca8e/pubs/frequentlyaskedquestionsfaqs.htm#2006>.

² TSCA 8(e) Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33129, 33138 (June 3, 2003) (the “2003 Guidance”) (replacing Statement of Interpretation and Policy, 43 Fed. Reg. 11110 (Mar. 16, 1978)). Notably, the 2003 Guidance retained -- without modification -- the core reporting criteria established in the original 1978 guidance, including the criteria discussed in this document for reporting of “non-emergency situations of chemical contamination involving humans and/or the environment”.

approach that considers both the numbers of persons exposed (or potentially exposed) and at what levels relative to the seriousness of toxic effects associated with the chemical. Many companies have been relying on these Part V(b)(1) criteria to determine the reportability of biomonitoring information.

In particular, Part V(b)(1) provides in pertinent 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).

As the foregoing reflects, Part V(b)(1) establishes the following three prongs -- all of which must be satisfied -- in order for information to qualify for 8(e) reporting:

- ⇒ The data "pertains to *widespread and previously unsuspected* distribution in environmental media of a chemical substance or mixture";
- ⇒ The chemical substance or mixture is "*known to cause serious adverse effects*"; *and*
- ⇒ Other information indicates "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"

The FAQ appears to acknowledge the "known to cause serious adverse effects" prong as a pre-requisite for 8(e) reporting,³ but does not even recognize as key factors in the 8(e) analysis -- let alone address -- the "widespread", "previously unsuspected", or "significant" criteria as

³ Under Part V(b)(1) of the 2003 Guidance, a chemical does not trigger 8(e) reporting unless it is "known to cause serious adverse effects", which means "cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or the inability to use a normal bodily function with a consequent relatively serious impairment of normal activities". 2003 Guidance, 68 Fed. Reg. 33138; see also *id.* at 33132 (in applying guidance on "non-emergency situations involving environmental contamination involving humans" "known to cause serious adverse effects" does not "mean that the effect must be conclusively shown and did not intend a higher standard of certainty" than that which applies to the reporting of effects information).

applied to biomonitoring results. Nor does the FAQ recognize the “sliding scale” approach articulated by EPA’s guidance.⁴

Second, instead of identifying what types of biomonitoring information qualify for “substantial risk” reporting, the FAQ focuses on when such information is not reportable due to EPA’s knowledge of the exposure. This guidance has limited value, given that biomonitoring may result in data not previously known to EPA, but also not of any particular “substantial risk” significance. Indeed, the FAQ does not address a number of factors that may bear on whether biomonitoring data trigger 8(e) reporting under the Part V(b)(1) “previously unsuspected”, “widespread” and “significant” exposure criteria and “sliding scale” approach, including the risk profile of the chemical; the properties of the chemical relevant to exposure duration and pathways; and the statistical significance, reliability and context of the biomonitoring data.

Third, the FAQ provides little insight into the “corroborative” exemption in Part VII(b) of the 2003 Guidance other than to say that the NHANES data presented in the CDC’s “National Report on Human Exposure to Environmental Chemicals” is “known to the Administrator” for purposes of applying the exemption. As such, the FAQ leaves unaddressed questions of what factors may be relevant in applying the “corroborative” exemption to biomonitoring data sets and what other types of data, beyond NHANES, may qualify as “known” to the Administrator for purposes of the exemption.

B. Other EPA Guidance on Human Biomonitoring and Section 8(e)

EPA’s long-standing TSCA 8(e) guidance dating back to 1978 and reaffirmed in the 2003 Guidance does not expressly address biomonitoring information. Despite its limitations, therefore, the September 2006 FAQ constitutes the only explicit EPA statement on the

⁴ Notably, in connection with the 2003 Guidance, EPA explicitly recognized that such a “sliding scale” applies to Part V(b)(1) situations:

EPA agrees that for situations of environmental contamination a “sliding scale” approach, *i.e.*, weighing the toxicity or exposure relative to the seriousness of the effect or the magnitude of the exposure is difficult to employ. However, companies would still need to judge the seriousness of the toxicity of the contaminant, the extent of the contamination, and the likelihood of actual exposure.

EPA, “Comment and Response Document for Revised Policy Statement of Section 8(e) of TSCA”, OPPT-2002-0067-0002 (received Feb. 20, 2003) (“Feb. 2003 Response to Comments”) at 19-20, *available at* www.regulations.gov (search under EPA Docket No. OPPT-2002-0067 and select item 2).

application of Section 8(e) to human biomonitoring data. As discussed above, however, the Part V(b)(1) criteria -- which make reference to “chemical contamination involving humans” -- would seem applicable to human biomonitoring data and are being relied on by many companies to make reporting judgments. Yet, the FAQ does not even acknowledge these criteria.

The recent 2004 and 2005 enforcement actions against DuPont involved human biomonitoring information in part,⁵ and hence, provide an additional consideration for companies striving to understand EPA’s views. These actions were settled, however, without any clear articulation as to why EPA believed the biomonitoring information in question warranted 8(e) reporting; whether and how EPA expects companies to apply the Part V(b)(1) guidance to biomonitoring information; and what biomonitoring information EPA regards as appropriate and not appropriate for 8(e) reporting.

II. NEED FOR ADDITIONAL GUIDANCE ON THE CHARACTERISTICS THAT CAN MAKE HUMAN BIOMONITORING INFORMATION 8(e) REPORTABLE

Read literally and in isolation from EPA guidance, the FAQ suggests that all human biomonitoring information on a chemical “known to cause serious adverse effects” triggers 8(e) reporting unless the information qualifies as corroborative of data already “known” to the EPA Administrator. Not only, as discussed in Part I above, does such a suggestion ignore the “substantial risk” statutory trigger and EPA’s longstanding Part V(b)(1) guidance, but it also does not accord with actual practice.

An analysis of submissions posted on EPA’s Section 8(e) website⁶ (see Attachment A) shows that since July 2004 through the most current information posted, only about 19 submissions have involved human biomonitoring information, of which 14 (74%) involved fluorochemicals. Another 3 submissions (16%) related to dioxin, a chemical of prominent concern to EPA. Only 2 submissions (10%) were unrelated to either fluorochemicals or dioxin.

⁵ In the Matter of E.I. du Pont de Nemours & Co., Docket Nos. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016 (complaint filed July 8, 2004; amended complaint filed Oct. 13, 2004) (the “2004 enforcement action”); In the Matter of E.I. du Pont de Nemours & Co., Docket No. TSCA-HQ-2005-5001 (complaint filed Dec. 6, 2004) (the “2005 enforcement action”).

⁶ Section 8(e) and FYI submissions are posted at <http://www.epa.gov/oppt/tsca8e/pubs/8eandfyisubmissions.htm>. At one time EPA posted submissions as far back as 2000. Currently only submissions from 2005 and four months from 2006 (January, February, June, and July) are posted.

These statistics demonstrate two important things.

First, the DuPont enforcement action does not appear to have triggered significantly increased reporting of biomonitoring information. Rather, the DuPont enforcement actions may have resulted, at most, in some additional fluorochemical submissions.

Second, the regulated community does not have any understanding or practice consistent with the implication of the FAQ that biomonitoring information for chemicals “known to cause serious adverse effects” -- regardless of the results and context -- should trigger 8(e) reporting.

ACC emphasizes that we do not currently possess information as to how many of our members have engaged in biomonitoring, and if so, what types, for what chemicals and how frequently. We do not wish to imply, therefore, that significant historical biomonitoring data exists that has not been submitted to the TSCA 8(e) docket. Clearly, however, some of our member companies have engaged in some biomonitoring, and we anticipate that more companies will potentially do so in the future as analytical techniques become further refined and economical and as risk assessment methods evolve to incorporate biomonitoring information.

Under the circumstances, the indeterminate resolution through settlement of the DuPont enforcement actions places the regulated community in a posture of having to assess the 8(e) reportability of biomonitoring data based on the only part of EPA’s long-standing guidance that appears relevant -- Part V(b)(1) -- and to grapple with an FAQ which is not consistent with that guidance and is otherwise incomplete. Moreover, this confusing compliance situation threatens to worsen as biomonitoring becomes more prevalent.

ACC urges EPA to rectify this situation by proposing for public comment as soon as possible meaningful additional guidance on the characteristics that can make biomonitoring information 8(e) reportable. In the spirit of cooperation, ACC offers its views in Part III below on approaches to augmenting the current Part V(b)(1) to provide such guidance.

III. RECOMMENDED CRITERIA FOR REPORTING BIOMONITORING INFORMATION

A. Biomonitoring Information That Correlates Adverse Effects With Internal Levels

Most biomonitoring provides information about concentrations of chemicals in the human body and not about health effects.⁷ As EPA has observed, “contamination is not an ‘effect’”, and “[f]or reporting under Part V(b)(1) effects do not need to be observed. The observation of health or environmental effects would be reported under Part V(a) and (b)(2-5) respectively.”⁸

Some studies produce both biomonitoring results and adverse effects in humans, thus allowing a correlation between biomonitoring levels and adverse effects. Such studies should be considered for Section 8(e) reporting under the health effects portion -- Part V(a) -- of the 2003 Guidance.

B. Biomonitoring Information Indicating That a Chemical “Known to Cause Serious Adverse Effects” Has a Long Residence Time in the Human Body

For a chemical “known to cause serious adverse effects” under EPA guidance, residence time in the body can be an important factor in assessing whether monitored concentrations in the body may qualify as

⁷ EPA has stated at http://www.epa.gov/hhrp/quick_finder/biomarkers.html that “[w]ith advanced technologies, it is now possible to measure very low levels of many environmental chemicals or their metabolites in biological fluids. Although detection of a specific biomarker provides information that exposure has occurred, it often provides little information to determine whether there is a health risk, or what the levels, sources, or pathways of exposure might be.”

Similarly, as the CDC’s Third National Report on Human Exposure to Environmental Chemicals (2005) at 4, *available at* <http://www.cdc.gov/exposurereport/3rd/>, counseled: “Advances in analytical methods allow us to measure low levels of environmental chemicals in people, but separate studies of varying exposure levels and health effects are needed to determine which blood or urine levels result in disease. These studies must also consider other factors such as duration of exposure.”

The National Research Council report entitled “Human Biomonitoring for Environmental Chemicals” also states: “To . . . [evaluate the risk associated with the amount of chemical found in the body], one needs to develop a relationship between biomarker concentration and toxic response, a relationship that is not commonly derived in standard toxicological practice.” <http://www.nap.edu/catalog/11700.html> (p. 158).

⁸ Feb. 2003 Response to Comments at 18.

“widespread” or “significant”. In addition, however, some biomonitoring, such as that in persons previously removed from exposure to a chemical, can itself provide important information on the time needed to eliminate the chemical from the body (*i.e.*, biological half-life). When such information on a chemical “known to cause serious adverse effects” indicates that the residence time in the human body is long (*e.g.*, a number of years), Section 8(e) reporting may be appropriate.⁹

C. Biomonitoring Information Indicating “Previously Unsuspected” and “Significant” or “Widespread” Exposure

As discussed above, Part V(b)(1) establishes the following three criteria -- all of which must be satisfied -- in order for information to qualify for 8(e) reporting:

- ⇒ The data "pertains to *widespread and previously unsuspected* distribution in environmental media of a chemical substance or mixture";
- ⇒ The chemical substance of mixture is "*known to cause serious adverse effects*"; and
- ⇒ Other information indicates "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"

As these criteria indicate, an 8(e) reporting obligation should not exist for biomonitoring information unless the chemical covered by the information is “known to cause serious adverse effects” based on toxicology and other existing data. For biomonitoring information on such a chemical, the 8(e) reporting obligation should depend upon whether the information indicates “previously unsuspected” exposure that is either “widespread” or “significant”. In applying these Part V(b)(1) criteria to biomonitoring information, it is appropriate to distinguish between occupational and non-occupational settings.

1. Occupational Biomonitoring

Occupational biomonitoring has been a long-standing industrial hygiene tool for certain chemicals through use of Biological Exposure Indices (“BEIs®”) published by the American Conference of Governmental

⁹ Some biomonitoring submissions under Section 8(e) have provided such information. See 3M submissions supporting calculation of a half-life for some fluorochemicals in the blood of workers, 8EHQ-0302-00373 (Mar. 19, 2002); FYI-0501-1378 (Apr. 25, 2001); status report on 8EHQ-1180-0373S, 8EHQ-1180-0374S, 8EHQ-0281-0373S Supplement, 8EHQ-0281-0374S Supplement (Apr. 21, 1981).

Industrial Hygienists (“ACGIH®”)¹⁰ and similar exposure limits. A variety of factors, including analytical advances and legal changes in European laws, may result in occupational biomonitoring for more chemicals in the future.

In evaluating occupational biomonitoring information for 8(e) reporting, it is important to bear in mind EPA’s 2003 Guidance on “previously unsuspected” exposures in the occupational setting. As this guidance indicates, exposures at routine levels to chemicals known, based on production activities and product uses, to be present in the workplace should not trigger an 8(e) reporting obligation:

. . . [In the case of products,] [k]nown toxic constituents, such as may be listed in the MSDS, even if widely commercially distributed would not trigger section 8(e) reporting.

Workplace exposure would be treated similarly. It would need to be previously unsuspected by EPA, result in contamination to major areas of the work site thus leading to actual or potential exposure, and have known, significant toxicity. Contamination of workplace air or surfaces by substances known to the manufacturer and EPA, such as OSHA regulated substances, would not need to be examined for section 8(e) reporting under Part V(b)(1) because they are not “previously unsuspected”.¹¹

In addition to not being “previously unsuspected”, workplace exposures to known contaminants should not qualify as either “significant” or “widespread” unless those exposures reach extraordinary levels. As the note to Part V(b)(1) indicates, environmental contamination below reference values, such as MCLs, RfDs, and RfCs, is *per se* not “significant”. The note also indicates, however, that even when exposures exceed such reference values, 8(e) reporting is not automatic, but an evaluation of “significant” and “widespread” must occur based on the

¹⁰ ACGIH® currently has BEIs® for about 47 chemicals or groups of chemicals. 2007 TLVs® and BEIs®.

¹¹ This language comes from a February 2003 Response to Comments document issued in conjunction with the 2003 Guidance. As it indicates, the “previously unsuspected” criterion for “non-emergency situations of chemical contamination involving humans and/or the environment” limits reporting of workplace contamination to circumstances involving either chemicals not believed to be present or chemicals known to be present, but being measured at extraordinary levels. Feb. 2003 Response to Comments, at 15. See also id. at 9 (“Known constituents of products, substances for which companies have permits to discharge and substances monitored in workplace air are not ‘previously unsuspected’.”).

“sliding scale” approach that weighs the seriousness of the toxic effects associated with the chemical relative to exposure circumstances.¹²

In many cases, occupational biological monitoring is performed to assess the effectiveness of the industrial hygiene controls. Elevated results normally occur as isolated events. Once the source for such results is identified through investigation, controls are upgraded as appropriate, and the biological levels monitored drop. Unless the chemical has a long biological half-life, it is unlikely in most workplaces that routine biological monitoring would show recurring elevated levels.

In applying the “significant” and “widespread” criteria to occupational biomonitoring information, relevant reference values may include regulatory levels for worker removal from exposure (such as OSHA standards),¹³ ACGIH BEIs and internal company health-based guidelines. Notably, exposure levels even several multiples of such reference values should not automatically trigger 8(e) reporting, just as environmental contamination in excess of an MCL, RfD, or RfC is not necessarily reportable.

Indeed, numerical exceedance of such reference values does not automatically equate to a biologically significant event. The precision of the analytical methodology needs to be interpreted in light of both the stringency of the risk method underlying a value and the exposure context. Just as exceedance of a RfD does not necessarily signal impending adverse health effects, exceedance of a biomonitoring standard or guidance value likewise does not always signify an impending significant health threat.¹⁴

¹² 2003 Guidance, 68 Fed. Reg. 33138. (“From time to time EPA establishes concentrations of various substances in different media that trigger a regulatory response or establish levels that are presumed to present no risk to human health or the environment. For example, EPA establishes Maximum Contaminant Levels (MCLs) in drinking waters, Ambient Water Quality Criteria for receiving bodies of water and Reference Doses(RfDs) or Concentrations (RfCs). For the purposes of section 8(e), information about contamination found at or below these kinds of benchmarks would not be reportable. Conversely, information about contamination found at or above benchmarks that trigger regulatory requirements, such as Resource Conservation and Recovery Act (RCRA) Toxicity Characteristic Limits, is to be considered for possible reporting, based on potential exposure to humans and/or non-human organisms and other relevant factors.”)

¹³ See, e.g., the following OSHA standards: lead, 29 C.F.R. § 1910.1025(k); cadmium, 29 C.F.R. § 1910.1027(l)(3).

¹⁴ EPA has supported this viewpoint in its IRIS guidance, stating in pertinent part:

The RfD is useful as a reference point from which to gauge the potential effects of the chemical at other doses. Usually, doses

A BEI, for instance, “generally indicates a concentration below which nearly all workers should not experience adverse health effects.”¹⁵ Similarly, standards for worker removal build in a wide margin of safety, and EPA presumably does not want, for example, to learn of every employee in a lead foundry removed from exposure due to biomonitoring results.

In sum, only occupational biomonitoring levels significantly elevated above reference levels should be considered for reporting. For example, one Section 8(e) submission has involved occupational biomonitoring results of more than 5x above regulatory levels.¹⁶

2. Non-Occupational Biomonitoring

Applying the “previously unsuspected”, “significant” and “widespread” criteria outside of the occupational setting raises different considerations. In contrast to the EPA guidance on workplace contamination, EPA has indicated that off-site contamination generally qualifies as “previously unsuspected”¹⁷ and must be evaluated for 8(e) reporting based on whether the potential or actual exposures that may

less than the RfD are not likely to be associated with adverse health risks, and are therefore less likely to be of regulatory concern. As the frequency and/or magnitude of the exposures exceeding the RfD increase, the probability of adverse effects in a human population increases. However, it should not be categorically concluded that all doses below the RfD are “acceptable” (or will be risk-free) and that all doses in excess of the RfD are “unacceptable” (or will result in adverse effects).

USEPA Reference Dose (RfD): Description and Use in Health Risk Assessments
<http://www.epa.gov/iris/rfd.htm>

¹⁵ ACGIH, 2006 TLVs and BEIs at 93.

¹⁶ 8EHQ- number unavailable (Apr. 20, 2006) (Dow submission of occupational urinary arsenic biomonitoring in South Africa at levels above a South African regulatory level for workers).

¹⁷ Feb. 2003 Response to Comments, at 9 (“Contamination by a substance that was ‘previously unsuspected’ is information that is not known to the Agency. For instance, it would include information about the discovery in off-site ground water of a substance that had been manufactured at the site for many years. It may not be surprising given the production history of the substance, but it is new information about actual, measured contamination. Manufacture, processing and distribution in commerce of substances does not presuppose environmental contamination or knowledge about such contamination by EPA.”).

result from such contamination qualify as “significant” or “widespread” using the “sliding scale” approach.¹⁸

In applying the “sliding scale” approach, a variety of factors may be relevant to assessing the reportability of the non-occupational biomonitoring information. These factors include, among others:

- ⇒ The risk profile of the chemical relative to the biomonitoring data (*e.g.*, relevance of the biomonitoring data to toxicological endpoints of concern; *e.g.*, how data compare to health-based reference levels and/or to risk assessment tools, such as Margins of Exposure (MOEs)).
- ⇒ The properties of a chemical bearing on exposure duration, pathways and levels, such as a chemical’s persistence, bioaccumulation potential, toxicokinetics and transport mechanisms.
- ⇒ The statistical significance of the biomonitoring data.

In a non-occupational setting, health-based reference values represent one important tool for assessing “significant” and “widespread” exposures. Occupational reference values may not be appropriate for such assessment due to the presence of subpopulations absent from the workplace (*e.g.*, children; elderly). If a non-occupational reference value has been established as a safe level, however, then biomonitoring indicating presence in community residents at or below that level need not be considered for reporting. Moreover, presence even slightly above such a reference value likewise may not trigger reporting, depending upon the factors identified above.

In the absence of reference values, background levels of exposure may prove relevant for assessing biomonitoring information as “significant” or “widespread”. The September 2006 Q&A referred to CDC report on NHANES data as “known to the Administrator”, but the report may also effectively establish background levels of chemicals in the general population which can then be used as benchmarks for determining whether the biomonitoring information indicates exposures elevated above background. Similarly, biomonitored levels in human cohorts reported in the scientific literature can serve as another resource to establish background levels.¹⁹

¹⁸ Companies should thus consider whether or not contamination is found off-site, and if it is, the amount, extent, and/or pattern of contamination and any other relevant factors. Feb. 2003 Response to Comments, at 14.

¹⁹ EPA appears to agree with this proposition as some of the allegations in the 2005 DuPont enforcement action involved elevated levels in community residents as compared to background that was established through published biomonitoring studies performed by 3M and others. An additional Count VIII, raised for the first

As CDC has emphasized, background levels established in NHANES do not necessarily imply anything about harmful levels.²⁰ Similarly, EPA has recognized that

[w]ith advanced technologies, it is now possible to measure very low levels of many environmental chemicals or their metabolites in biological fluids. Although detection of a specific biomarker provides information that exposure has occurred, it often provides little information to determine whether there is a health risk, or what the levels, sources, or pathways of exposure might be.²¹

Consistent with these EPA and CDC views, biomonitoring information showing levels elevated above background sometimes may -- but not necessarily always will -- indicate “significant” or “widespread” exposure. In this situation, the 8(e) reporting judgment should depend upon the degree of elevation, the context and the toxicological profile and other information on the chemical.

Where no background levels have been established, biomonitoring information that essentially establishes such levels may qualify for reporting under the “sliding scale” approach. For example, some 3M submissions reported levels in pooled human serum purchased from regional blood banks, and thus not representing populations in the local community. These submissions are in the nature of NHANES-type data of which EPA was not previously aware.²²

In using background levels, only levels elevated several times above background generally should be considered for reporting under Section 8(e) unless the biomonitoring information relates to (or tends to demonstrate a nexus to) a unique and identifiable exposure source and/or exposure pathway. Examples of such information may include, but are not limited to, the following:

time in the Consent Agreement and Final Order (Dec. 14, 2005), *available at* <http://www.epa.gov/compliance/resources/cases/civil/tsca/dupont121405.html>, alleged failure to submit information on PFOA levels in another 10 community residents.

²⁰ “As noted above, the presence of a chemical does not imply disease.” CDC, Third National Report on Human Exposure to Environmental Chemicals (2005) at 4, *available at* <http://www.cdc.gov/exposurereport/3rd/>.

²¹ http://www.epa.gov/hhrp/quick_finder/biomarkers.html

²² See 8EHQ-0501-0373 (May 15, 2001); 8EHQ-0601-0373 (June 7, 2001); 8EHQ-0302-00373 (Mar. 19, 2002); 8EHQ-0905-00373 (Aug. 25, 2005); 8EHQ-1205-00373 (Dec. 19, 2005).

- ⇒ **Biomonitoring information for persons with a known or reasonably suspected specific route of exposure to the chemical, such as: persons ingesting drinking water that contains the chemical; or persons residing in immediate proximity to an area with identified environmental presence of the chemical.**
- ⇒ **Biomonitoring information indicating the presence of the chemical in breast milk and/or in umbilical cord blood.**

Each of these examples are discussed in greater detail below.

a. **Biomonitoring Information in Non-Occupational Populations Indicating Presence of a Chemical “Known to Cause Serious Adverse Effects” From a Particular Exposure Pathway and Source of Exposure**

In the 2005 DuPont enforcement action, EPA asserted that biomonitoring results in community residents exposed to fluorochemicals through their drinking water “are 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.”²³ Notably, some Section 8(e) submissions have also provided this type of source-related biomonitoring information for community residents.²⁴ Consistent with this approach, where sources and pathways of exposure to a toxic chemical are identifiable and limited, information on resulting body burden in exposed non-occupational populations may be considered for reporting under Section 8(e).

b. **Biomonitoring Information Indicating that a Chemical “Known to Cause Serious Adverse Effects” Can Cross the Placenta or Show Up in Breast Milk**

Count 1 in the 2004 DuPont enforcement action involved one data point that was characterized by EPA as pertaining to information that demonstrated the rate of movement of PFOA from a mother to her fetus.²⁵ In the action, EPA declared:

²³ Complaint ¶ 38 (Dec. 6, 2004), In the Matter of E.I. du Pont de Nemours & Co., Docket No. TSCA-HQ-2005-5001, *available at*: <http://www.epa.gov/compliance/resources/complaints/civil/mm/dupont2-pfoa-complaint.pdf>.

²⁴ See 8EHQ-1004-15723 (Oct. 5, 2004) (Dow submission of information about dioxin biomonitoring in community residents).

²⁵ EPA Memo at 6.

EPA considers the data to be highly significant because the Agency did not previously have any data from humans showing movements of PFOA from mother to fetus, only data from lab animals.²⁶

Toxicologists routinely determine that some chemicals can pass through the placentas of laboratory animals, and little difference exists between humans and other mammals in that regard. For scientists, it is expected that some substances absorbed by pregnant women will be distributed in the bloodstream, and therefore, also come in contact with the developing fetus.²⁷ Nevertheless, due to the policy considerations, it may be appropriate for the Agency to request reporting of such information. Under the same rationale, the Agency may request reporting of biomonitoring information that indicates the presence of a chemical “known to cause serious adverse effects” in breast milk, irrespective of the concentration.²⁸

D. Exemptions for Certain Human Biomonitoring Information

As further assistance to the regulated community, EPA should clarify the scope of some existing exemptions from reporting already included in the 2003 Guidance as applied to common biomonitoring situations.

1. Unreliable Information

Under Part VI of the 2003 Guidance, information must “reliably ascribe” the observed results to the chemical to qualify for reporting. Accordingly, information without sufficient reliability does not trigger an 8(e) reporting obligation. Although “reliability” does not require that information be conclusive or definitive, it does require that consideration be given to whether the information stems from the application of minimum professional standards for data recording, methodology, and so

²⁶ Id.

²⁷ See Comments of the American Chemistry Council on EPA’s Supplemental Guidance for Assessing Cancer Susceptibility from Earlylife Exposure to Carcinogens (SGACS) (May 5, 2003), 68 Fed. Reg. 17803, April 11, 2003 (With the striking advances in analytical chemistry, almost any substance a human comes in contact with should theoretically be detectable using advanced human biomonitoring techniques. This would apply to the pregnant woman, the fetus and the nursing mother and infant. Furthermore, there is no scientific basis for presuming that the developing organisms and the infant are always more vulnerable or susceptible than the adult to risks from exposure to trace levels of chemicals in the environment.).

²⁸ An ACC submission reported that chemicals related to flame retardants had been detected in breast milk in Norway. 8EHQ-1203-15495 (Dec. 11, 2003).

forth. In addition, information may not be reportable if a “plausible link” does not exist with the chemical in question or if the information does not “reasonably support” the conclusions or premises that would trigger 8(e) reporting.²⁹

Reliability is a particularly important concept as applied to human biomonitoring information. It is becoming more common for third parties to generate biomonitoring results and present them with an advocacy -- as opposed to a scientific -- focus. Notably, different analytical techniques can produce vastly different results, and substantial expertise also can be required to avoid misapplication of analytical techniques when measuring a chemical at very low levels.

Consistent with the EPA guidance, companies should evaluate the reliability of biomonitoring information. In making a reliability judgment, it is important to recognize that the following types of information may not have sufficiently established reliability to trigger 8(e) reporting:

- ⇒ The biomonitoring information was generated through techniques that do not meet minimum professional standards for sample collection, storage and transport; analytical methodology; data recording; and so forth.
- ⇒ The biomonitoring information was generated by a third party and is available to the manufacturer, processor, user or distributor subject to an 8(e) compliance obligation in a form lacking sufficient other information to establish reliability.
- ⇒ The biomonitoring information reflects an implausible result -- *i.e.*, a result that other information about the chemical suggests may not be accurate -- and consists of a sample size lacking either statistical significance or other indicia of robustness.

2. Corroborative Information

Under Part VII(b) of the 2003 Guidance, otherwise reportable information does not need to be submitted if it merely is corroborative of a “well-established serious adverse effect” already documented in the scientific literature.³⁰ Information is excluded from reporting as corroborative if it “essentially duplicates and/or confirms an existing and

²⁹ See 2003 Guidance, 68 Fed. Reg. 33139; see also *id.* (An effects study will trigger reporting if it “reliably ascribe[s]” the observed effect to a chemical, group of chemicals, process or effluent.); TSCA Section 8(e) Reporting Guide (June 1991) (the “Reporting Guide”); July 1989 TSCA Section 8(e) Q&A Document (incorporated into the 1991 Reporting Guide) at 7.

³⁰ Id.

well-documented understanding of a serious adverse effect of a particular chemical or mixture.”³¹ EPA has cited the following as examples of elements that must be present for one set of data to be considered corroborative of another: same “route of exposure, dose, species, strain, sex, time to onset of effect, a well-recognized/well-established serious adverse effect.”³²

The FAQ recognizes that the corroborative exemption should apply to human biomonitoring information, but does not address the factors that companies should consider in making that judgment. In general, biomonitoring information that correlates with background levels established through the National Health and Nutrition Examination Survey (NHANES) or through a study or multiple studies “known to the EPA Administrator” should be corroborative -- and not 8(e) reportable -- unless that information raises additional reporting considerations discussed above, such as the information indicates a long residence time, correlates to adverse effects or stems from a unique and identifiable exposure source and/or exposure pathway. Moreover, once biomonitoring information has been reported to EPA, subsequent biomonitoring information for the same chemical and same (or substantially similar) exposed population should be corroborative -- and not trigger 8(e) reporting -- where that information demonstrates comparable levels and does not raise new or different considerations that might make the subsequent information independently appropriate for reporting.

3. Biomonitoring Information Related to Persons Outside the United States

Part VII(h) of the 2003 Guidance generally limits environmental contamination information reportable under Part V(b)(1) to contamination in the United States:

“Substantial risk” information need not be reported under Section 8(e) if it: . . .

- (h) Is information of the kind under Part V.(b)(1) and (c) concerning a non-United States site provided the person who obtains the information does not have reason to believe that there is a substantial likelihood that the contamination will cause environmental contamination, of a nature that would be reportable under Part V.(b)(1) and (c), to occur in an area in the United States.

³¹ 58 Fed. Reg. at 37739.

³² Id.

By analogy, mere presence of a chemical “known to cause serious adverse effects” in humans outside of the United States should not be subject to the 8(e) reporting obligation. Clarity on this point is particularly important for multinational corporations, given that a number of foreign countries mandate extensive biomonitoring of workers.

This geographic limitation might not apply if the biomonitoring provides important information in addition to the fact of presence in the body, *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 on the time required to eliminate the chemical from the body. The geographic limitation also would not apply if the information has direct relevance to production or other commercial operations located in the United States and exposures in the United States resulting from those operations.³³

In the absence of clear EPA guidance, some of the human biomonitoring submissions have concerned populations outside the United States. One has conveyed additional information, such as that suggested above.³⁴ Others have reported concentrations in non-U.S. worker populations engaged in manufacturing operations similar to those in the United States.³⁵ A few others have addressed biomonitoring for non-US community residents.³⁶

³³ This approach would accord with that followed by EPA under the PMN program. See 40 C.F.R. 720.50(d)(3) (data need not be submitted for PMN review that related only to exposure of humans or the environment outside the U.S., but this exclusion does not exclude nonexposure data such as data on health effects (including epidemiological studies, ecological effects, physical and chemical properties, or environmental fate characteristics).

³⁴ See 8EHQ-1203-15495 (Dec. 11, 2003) (ACC report of a study indicating that flame retardant chemicals have shown up in breast milk in Norway).

³⁵ 8EHQ- number unavailable (Apr. 20, 2006) (Dow submission of occupational urinary arsenic biomonitoring in South Africa at levels above a South African regulatory level for workers); 8EHQ-0904-15666S (Sept. 17, 2004) (submission by an unnamed company of biomonitoring of workers for fluorochemicals in an unnamed country other than the U.S.); 8EHQ-0904-15663 (Sept. 7, 2004) (submission by MIC Specialty Chemicals of biomonitoring for fluorochemicals in Italian workers); FYI-0102-01378 (Dec. 20, 2001) (submission by 3M of biomonitoring for fluorochemicals in Dutch workers).

³⁶ 8EHQ-1004-15723 (Oct. 5, 2004) (submission by Dow of biomonitoring for dioxin in New Zealand community residents).

4. Biomonitoring Information Known to the Administrator From Third Party Websites

Part VII(a) of the 2003 Guidance³⁷ expanded the sources of information “known” to the EPA Administrator for 8(e) reporting purposes. Although this expansion has been enormously useful, ACC believes that further clarification is needed to account for the availability of information on the internet.

Under Part VII(a), the EPA Administrator is presumed to be adequately informed about substantial-risk information if such information is found in certain publicly disseminated sources. These include:

- ⇒ an EPA study or report;
- ⇒ an official publication or official report (draft or final) published or made available to the public by another Federal agency;³⁸
- ⇒ scientific publications, including bibliographic databases (*e.g.* Science, Nature, New England Journal of Medicine, Medline, Toxline, NIOSH RTECS, IUCLID, etc.);³⁹
- ⇒ a scientific database (*e.g.* Agricola, Index Medicus, Biological Abstracts, Dissertation Abstracts);
- ⇒ a news publication with U.S. circulation;
- ⇒ a radio or television news report broadcast in the United States;⁴⁰

³⁷ Id.

³⁸ As EPA has stated, however, it cannot be assumed that EPA is adequately informed of information that has been presented in a report by or to a U.S. Government agency (other than EPA), but has not been formally published or otherwise made available to the general public. Therefore, EPA takes the position that unpublished information contained in reports by or to any agency of the U.S. Government (other than EPA) must be reported under TSCA Section 8(e). Feb. 2003 Response to Comments, at 22-23.

³⁹ Articles published in a major scientific journal do not need to be submitted. EPA has explained that “major” means a journal from which articles routinely are abstracted on a major computerized abstract data base or in a major abstracting publication, such as Current Contents. Id. at 23.

⁴⁰ EPA has indicated, however, that “[g]enerators of the data have an obligation to report to EPA even if they release study results to the media because there is no assurance that the media report will accurately convey all the pertinent information on the situation to the public and EPA. The reporting exemption is not

- ⇒ a record of a public scientific conference held in the U.S. provided that information was captured accurately and disseminated publicly within 90 days; or
- ⇒ a presentation at a public scientific conference sponsored or co-sponsored by EPA, “where the subject information is presented by an EPA employee or contractor acting on behalf of EPA.”⁴¹

The wording of the 2003 Guidance would seem to allow for EPA “knowledge” based on public availability of the foregoing through the internet. For example, if a record of a public scientific conference held in the U.S. is posted on the internet within 90 days, then EPA would seem to have “knowledge” of that record for 8(e) reporting purposes. It would be useful to have EPA clarify this position.

Moreover, biomonitoring has attracted considerable interest from non-governmental organizations (“NGOs”). Several NGOs have publicized biomonitoring results either from pooled blood or from prominent individuals such as legislators through press releases that refer readers to their websites.⁴² Most often, this information is not published in scientific journals, its scientific reliability and accuracy cannot be discerned, and NGOs are not subject to Section 8(e). Companies, however, generally are not in a position to have any more information than contained in the press release and on NGOs’ websites -- information that is equally available to EPA. EPA should clarify, therefore, that information on third party websites, such as those of NGOs or universities, are considered known to the Administrator.⁴³

designed to alleviate generators of test or contamination data of their obligation to report substantial risk notices to EPA, because they do not have any control over when and what will be reported.” February 2003 Response to Comments, at 26.

⁴¹ Id.

⁴² See, e.g., Greenpeace International, “A Present for Life: Hazardous Chemicals in Umbilical Cord Blood” (Sept. 2005), *available at* <http://www.greenpeace.org/international/news/poisoning-the-unborn111?&CFID=6607887&CFTOKEN=10665897&MenuPoint=D-C>; Environmental Defence, “Toxic Nation: A Report on Pollution in Canadians” (Nov. 2005), *available at* <http://www.environmentaldefence.ca/reports/toxicnation.htm>; Pesticide Action Network North America, “Chemical Trespass: Pesticides in Our Bodies and Corporate Accountability” (May 2004), *available at* <http://www.panna.org/campaigns/docsTrespass/chemicalTrespass2004.dv.html>.

⁴³ Of course, this clarification should not apply to websites maintained by the regulated community, as Section 8(e) obligations should not be avoided simply by posting reportable information on a company or trade association website.

E. EPA Biomonitoring Guidance Should Be Applied Prospectively

In announcing its environmental contamination reporting criteria in the 2003 Guidance, EPA committed to enforce those criteria only prospectively:

Seventh, because of the number of changes made to the proposed guidance in the 1995 Federal Register notice and the fact that it represented a significant change from the original guidance suspended on June 20, 1991, the Agency concluded that the revised guidance when issued should be applied prospectively. This eliminates the need for companies to review files currently in their possession for information that may be subject to section 8(e) reporting in accordance with the revised guidance.⁴⁴

Under a similar rationale, EPA should apply its biomonitoring guidance prospectively:

- ⇒ The biomonitoring guidance will be an aspect of the Part V(b)(1) guidance that EPA decided should be applied prospectively.
- ⇒ The regulated community has not had adequate notice heretofore of what kinds of biomonitoring information EPA expects to receive under Section 8(e).
- ⇒ The burden on the regulated community of reviewing old files using the new guidance would be considerable.
- ⇒ The potential liability for reporting old biomonitoring results could be substantial.⁴⁵

⁴⁴ 68 Fed. Reg. 33129, 33133 (June 3, 2003).

⁴⁵ For example, in the 2004 DuPont enforcement action, EPA calculated the statutory maximum penalty for 20 years of daily penalties for DuPont's failure to submit a single biomonitoring document was \$183,837,500. EAB Memo at 6-7.

ATTACHMENT A

Section 8(e) and FYI Human Biomonitoring Submissions, July 2004 – Present

The following Section 8(e) or FYI human biomonitoring submissions have been made since the announcement of the first EPA complaint against DuPont in July 2004.

1. Submissions Related to Fluorochemicals (14)

- September 2004: In FYI-1004-01480, Taft, Stettinius & Hollister submitted information that DuPont had collected on PFOA (a fluorochemical) serum levels in 12 community residents.
- September 2004: In 8EHQ-0904-15663, MIC Specialty Chemicals, Inc. (through counsel) submitted a report discussing biological monitoring of workers exposed to PFOA in Italy.
- September 2004: In 8EHQ-0904-15663B, DuPont submitted a meeting report on a PFOA biological monitoring study of workers.
- September 2004: In 8EHQ-0904-15666S, an undisclosed company submitted information on levels of fluorochemicals in the blood of workers in another country.
- November 2004: In 8EHQ-1104-00394, DuPont submitted results of PFOA blood sampling for employees at its PFOA facility in West Virginia that was the subject of the class action.
- November 2004: In 8EHQ-1104-15856A, DuPont (through counsel) submitted 650 reports of monitoring and exposure studies, including PFOA human serum results of non-occupational blood testing.
- December 2004: As referenced in 8EHQ-1204-15856S, per EPA's request DuPont agreed to provide by December 10, 2004, PFOA-related occupational blood monitoring summary documents or reports, with underlying data to be submitted at a later date.
- January 2005: In 8EHQ-0105-0394, DuPont reported the results of analyses comparing serum PFOA levels with the results of blood and urine medical analysis of workers at its West Virginia PFOA facility.
- June 2005: In 8EHQ-0605-14837, 3M submitted a poster about urinary bladder endpoints in workers exposed to fluorochemicals.

- July 2005: In 8EHQ-0705-16101 (also classified as FYI-0705-01499), Little Hocking Water Association, whose wells contain PFOA allegedly from DuPont's West Virginia facility, provided a summary of blood sampling data from 25 community residents whose residential water is supplied by Little Hocking.
- August 2005: In 8EHQ-0905-00373, -00374, and -00394, 3M submitted an analytical report presenting data from 36 lots of commercially available normal pooled human blood purchased by 3M and screened for 16 fluorochemicals.
- September 2005: In 8EHQ-0905-15856, DuPont reported summary information provided by plaintiffs' counsel on PFOA blood testing being conducted on community residents pursuant to a screening program established through the settlement of the class action litigation.
- November 2005: In 8EHQ-1105-00373, 3M provided information on biomonitoring of workers and children of workers at a fluorochemical plant.
- December 2005: In 8EHQ-1205-00373, -00374, and -00394, 3M provided information on lots of commercially available normal pooled human serum screened for endogenous fluorochemicals.

2. Submissions Related to Dioxin (3)

- August 2004: In 8EHQ-0804-14151, Dow submitted information on an update to a previous dioxin mortality study including measurements of serum dioxin levels in workers.
- October 2004: In 8EHQ-1004-15723, Dow submitted a report by the New Zealand Ministry of Health entitled "A Study of 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) Exposures in Paritutu, New Zealand, Phase II: Serum Testing".
- July 2006: In 8EHQ-0706-14151C, Dow submitted additional information on an update to a previous dioxin mortality study including measurements of serum dioxin levels in workers.

3. Submissions Not Related to Fluorochemicals or Dioxin (2)

- December 2004: In 8EHQ-1204-15867 DuPont submitted preliminary blood biomonitoring information on elevated concentrations of o-toluidine in the blood of European 1,3-di-ortho-tolylguanidine workers.

- April 2006: In a submission for which the 8EHQ- number is unavailable, because not posted, Dow submitted results of urinary arsenic testing in South Africa.

Source: Submissions posted at <http://www.epa.gov/oppt/tsca8e/pubs/8eandfyisubmissions.htm> and ACC member information.

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