

Washington Watch

Toxicogenomic Data and Federal Regulatory Settings: Managing the Avalanche of Data

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Toxicogenomic data are expected to find significant regulatory application in three areas:

- susceptibility -- identifying subpopulations and life stages uniquely susceptible to environmental factors;
- predictive toxicology -- facilitating high-throughput chemical screening for potential adverse impacts and assisting in prioritizing chemicals believed to be most potentially toxic; and
- disease mechanisms -- helping elucidate a substance's mode of action to define better the dose-response continuum.

While there is general consensus that these data will be in abundant supply and ultimately very useful, there is less consensus on how to interpret the data and how best to manage them for purposes of maximizing their utility in federal regulatory settings.

The U.S. Environmental Protection Agency (EPA) acknowledges this in its final December 2004 document entitled *Potential Implications of Genomics for Regulatory and Risk Assessment Applications at EPA*, prepared by the Agency's Science Policy Council Genomics Task Force Workgroup (the "Genomics Task Force White Paper").¹

As EPA notes in the Genomics Task Force White Paper, "understanding genomic responses with respect to adverse ecological and/or human health outcomes is far from established."² Accordingly, the actual application of genomic data any time soon for regulatory standard-setting purposes, or the use of gene expression data to classify toxic and non-toxic effects, would seem unwise. Nonetheless, the temptation to use these data, despite their nascent stage of development, will be hard to resist.

Outlined below are examples of recent government activities that illustrate the challenges now being confronted by agencies and stakeholders in the human and ecological health areas when using genomic data in regulatory settings. These illustrations are only a glimpse of the shape of things to come.

OMB's Final Information Quality Bulletin for Peer Review

The Office of Management and Budget (OMB) issued its *Final Information Quality Bulletin for Peer Review* on December 15, 2004 (the "Final Bulletin").³ The Final Bulletin sets forth minimum requirements for the peer review of scientific information and

stricter minimum requirements for the peer review of “highly influential scientific assessments” disseminated by the federal government.

The Final Bulletin was issued pursuant to the Information Quality Act (IQA), a supplement to the Paperwork Reduction Act. The IQA requires, among other things, that OMB (i) issue guidelines to develop and oversee the implementation of policies, principles, standards, and guidance applying to federal agency dissemination of public information⁴ and (ii) provide policy and procedural guidance to federal agencies on ensuring and maximizing the quality, objectivity, utility and integrity of information that is disseminated by federal agencies.⁵

Identification of Potential Regulatory Uses

Much has been written about potential regulatory applications of genomic data by the federal government, and about their application and potential use and misuse in legal proceedings, most particularly toxic tort litigation.⁶ Importantly, the Genomics Task Force White Paper carefully identifies representative activities in key EPA program offices that are potentially affected by genomic information, providing a useful blueprint for tracking the promise these data hold in a diverse range of regulatory and policy areas.

The activities identified include, for example, the use of genomic data in the voluntary High Production Volume (HPV) Program screening process to validate category groupings in HPV and other future high-volume chemical screening programs; to supplement computer model results pertinent to chemicals on the Safe Drinking Water Act Contaminant Candidate List for purposes of hazard estimation and prioritization; and to monitor for adverse effects in areas surrounding specific/contaminated sites.⁷

IQA Guidelines and Peer Review Standards

The scientific information supporting any such application must be consistent with the IQA Guidelines issued by OMB in 2002,⁸ and with parallel federal agency-specific guidelines that were required to be issued in October 2002.⁹

An important component of the IQA Guidelines is the presumption that data and other analytic results are subject to some form of peer review. Recognizing that some agency peer review procedures are better than others, OMB issued its *Revised Information Quality Bulletin for Peer Review* on April 15, 2004,¹⁰ and its Final Bulletin in December 2004. The goal of the Final Bulletin is to ensure the quality of scientific and technical information that federal agencies rely upon in formulating policy, guidance, and regulations.

The Final Bulletin requires varying degrees of peer review rigor, depending upon the nature of the information being reviewed. Scientific information is broadly defined to include “factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences.”¹¹ The Final Bulletin states that “each agency shall conduct a peer review on all influential scientific information that the agency intends to disseminate.”¹²

Exemptions from Peer Review Requirements

The Final Bulletin includes several exemptions. In most cases, agencies “need not have peer review conducted on information” that is:

- related to national security, foreign affairs, or negotiations involving international trade or treaties;
- disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, or site-specific determination), unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings;
- a health or safety dissemination where the agency determines that the dissemination is time-sensitive (e.g., findings based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began);
- an agency regulatory impact analysis or regulatory flexibility analysis;
- routine statistical information released by federal statistical agencies;
- certain accounting, budget, actuarial, and financial information.¹³

“Influential Scientific Information”

In the Final Bulletin, “influential scientific information” is defined as scientific information that “the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.”¹⁴

“Highly Influential Scientific Assessments”

Federal agency reliance on genomic data can be expected to be considered influential scientific information. If so, it would trigger the higher level of peer review required for “highly influential scientific assessments.”

The Final Bulletin defines a “scientific assessment” as an “evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information.”¹⁵

“Highly influential scientific assessments” are defined under the Final Bulletin as those that “the agency or the Administrator determines to be a scientific assessment that: (i)

could have a potential impact of more than \$500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest.”¹⁶

Level of Peer Review Required

Peer reviews of highly influential scientific assessments are most rigorous, and leave less consideration regarding the form of peer review to the agency’s discretion. Other, more rigorous, conditions also apply to highly influential scientific assessments with respect to the composition of the peer review panel and opportunities for public comment.¹⁷

While there may be debate, EPA’s initial and ongoing forays into regulatory initiatives that rely upon gene expression data for regulatory purposes would appear to trigger the most stringent level of peer review. Application of these standards in practice, however, raises interesting issues.

In the Genomics Task Force White Paper, EPA discusses the example of “a pesticide registrant [that] has cited several published genomic articles as part of their data package submission for product registration to EPA’s Office of Pesticide Programs. The data were submitted to propose an alternative mode of action that would affect human health assessment conclusions.”¹⁸

Assuming that the provisions of the Final Bulletin apply, or EPA determines that the “influential dissemination” is likely to have precedent-setting influence (and thus waives any potential exemption), would the Agency’s reliance on the registrant-supplied genomic data confer upon the data the status of “influential scientific information,” thus subjecting them to peer review?

Presumably, if the genomic data are included in published articles, they have been peer reviewed. It is unclear, however, whether the peer review they have undergone would be considered to be at a level consistent with the Final Bulletin.

Similarly, would EPA’s scientific assessment of these registrant-submitted genomic data, were it to result in a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) product registration, constitute a “highly influential scientific assessment” that triggers the highest level of peer review? If so, what would be subject to peer review -- only the EPA assessment, or the data underlying the assessment?

OMB notes in the Final Bulletin that it “does not directly cover information supplied to the government by third parties (e.g., studies by private consultants, companies . . . or research institutions such as universities).”¹⁹

Importantly, the Final Bulletin also notes that “if an agency plans to disseminate information supplied by a third party (e.g., using this information as the basis for an agency’s factual determination that a particular behavior causes a disease), the requirements of the [Final] Bulletin apply, if the dissemination is ‘influential.’”²⁰

Unanswered Questions

These issues, and related others, are open questions under the Final Bulletin. When federal agencies begin to use and/or rely upon genomic data for regulatory purposes, as they are expected to do in the years to come, questions almost certainly will arise regarding whether the high standards of the Final Bulletin have been met.

Similarly, private parties need to think carefully about:

- the implications of submitting genomic data to federal agencies for regulatory purposes,
- the implications of IQA policies when designing and implementing research initiatives to support product registrations and approvals, and
- the impact of these policies on other scientific data generated in connection with regulatory outcomes.

How these questions will be answered, and in what forum, is unclear.

Genomic Data and Adverse Effects Reporting

Another interesting question of particular concern to the chemical community relates to the relative lack of guidance pertinent to genomic data with respect to reporting under Section 8(e) of the Toxic Substances Control Act (TSCA) and its counterpart FIFRA Section 6(a)(2).

This lack of guidance has been noted repeatedly in articles over the last several years, but is perhaps even more compelling now in light of two EPA enforcement actions filed in 2004 against DuPont under TSCA Section 8(e).²¹

These enforcement actions, which are discussed in more detail below, break new ground on several fronts.²² Among the concerns raised by EPA's actions are how an adverse effect is defined for purposes of Section 8(e) reporting obligations, and the potential liability a company might face for establishing a voluntary internal standard.

Background: TSCA Section 8(e)

Under TSCA Section 8(e), any person who manufactures, imports, processes, or distributes a chemical substance or mixture, and who obtains information which reasonably supports the conclusion that the chemical substance or mixture poses a substantial risk of injury to human beings or the environment, must provide the information to EPA immediately.²³

EPA's policy on Section 8(e) reporting addresses two types of reportable information -- human health effects information and environmental contamination.

Human Health Effects Reporting

EPA's TSCA Section 8(e) policy identifies the human health effects that warrant reporting as follows:

The Agency considers effects for which substantial-risk information should be reported to include the following.

(a) *Human health effects.* (1) Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of 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.

(2) Any pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation.²⁴

Environmental Effects Reporting

EPA identifies in its policy the non-emergency situations involving environmental contamination that warrant reporting as follows:²⁵

The Agency considers effects for which substantial-risk information should be reported to include the following. . . .

(b) *Non-emergency situations involving environmental contamination; environmental effects --* (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). Information concerning the detection of chemical substances contained within appropriate disposal facilities such as treatment, storage and disposal facilities permitted under [the Resource Conservation and Recovery Act (RCRA)] should not be reported under this part.²⁶

To fall within the type of environmental effects discussed in the policy, the information must, with other criteria, pertain to “widespread” and “previously unsuspected distribution in environmental media.”²⁷

In this regard, on January 12, 2005, EPA issued a *Federal Register* notice correcting certain language that the Agency states was inadvertently omitted from its June 3, 2003, TSCA Section 8(e) reporting guidance.²⁸

EPA’s 2003 guidance clarified certain aspects of its 1978 TSCA Section 8(e) reporting guidance and republished major portions of the 1978 TSCA Section 8(e) Policy Statement. EPA’s January 12, 2005, notice states that EPA “merely re-inserts, verbatim,” certain language from the 1978 TSCA Section 8(e) Policy Statement into the June 3, 2003 guidance.

Relevant for present purposes, the notice also announces the addition of questions and answers on the reportability of environmental releases to the Q&A section of EPA’s TSCA Section 8(e) web page. Several of them would appear to relate directly to the facts presented in the DuPont actions.²⁹

The DuPont Enforcement Actions

How TSCA Section 8(e) requirements might apply to genomic data is illustrated by recent EPA enforcement actions against DuPont. These enforcement actions do not themselves involve genomics, but do raise numerous issues that are likely to become important to the genomics debate.

On July 8, 2004, EPA issued a complaint against DuPont alleging two violations of the reporting requirements imposed by TSCA Section 8(e) and one violation of RCRA.³⁰ DuPont filed its answer to the first EPA complaint on August 11, 2004.³¹ EPA issued a second complaint on December 6, 2004, alleging an additional TSCA Section 8(e) violation.³²

EPA’s allegations would, if upheld, potentially set a new standard for Section 8(e) reporting.³³ All the alleged violations pertain to data relating to perfluorooctanoic acid (PFOA), which has been the subject of significant attention since data were released showing a general background level of five parts per billion (ppb) in the blood of the U.S. population. The specific TSCA Section 8(e) allegations are discussed below.

Transfer of PFOA from Blood of Mother to Fetus (First Complaint)

EPA claims that under TSCA Section 8(e), DuPont should have reported to the Agency in 1981 the results of a single blood sample which suggested that a trace amount of PFOA could cross the human placenta if it is present in the maternal blood.³⁴

DuPont asserts that EPA’s scientists knew in 1981 that a chemical like PFOA would travel through the placenta. In addition, in 1982, DuPont provided to EPA the results of an animal study confirming that PFOA would cross the placenta.³⁵

DuPont states that the TSCA Section 8(e) reporting requirement is triggered “only when the information reasonably supports the conclusion that exposure to a chemical actually presents a ‘substantial risk to human health.’”³⁶ Based on the testing that has been done, DuPont claims that prenatal exposure to PFOA does not cause such a risk, and that there was thus no “substantial risk” to trigger reporting requirements.³⁷

DuPont further states that TSCA Section 8(e) does not require a company to report information if EPA is already “on notice” of the information.³⁸

Presence of PFOA in Public Water Supplies at Levels above Voluntary Internal Standard (First Complaint)

Perhaps the most controversial allegation of the First Complaint is EPA’s claim that DuPont should have reported the results of water sampling that found levels of PFOA in excess of DuPont’s voluntary internal guideline, even though that guideline was below regulatory requirements.³⁹

DuPont’s answer questions the legal basis for this portion of the complaint, and claims that EPA

seeks to punish DuPont for establishing a level of safety that exceeds EPA’s requirements and sends a message to the regulated community that it should never set a voluntary goal for an unregulated chemical for fear that EPA will label any exceedance of that goal a “substantial risk” that must be reported to the Agency.⁴⁰

DuPont cites EPA’s own guidance on TSCA Section 8(e) reporting, which states that when EPA sets an acceptable level in drinking water, a company that detects the chemical in drinking water at concentrations below that level does not have an obligation to report under TSCA Section 8(e).⁴¹

DuPont states that it undertook a program of minimizing its plant emissions to reach a self-imposed goal of reducing the PFOA level in drinking water so that there would be a 3,000-fold margin of safety.⁴²

DuPont also notes that the levels which EPA claims DuPont failed to report (0.8 to 3.9 ppb) are 38 to 185 times lower than the 150 ppb drinking water level which the C8 Assessment of Toxicity Team, a multi-agency panel of scientists (including several from EPA) concluded in 2002 poses “no risk of deleterious effects” to human health.⁴³

Presence of PFOA above Background Level in Blood Samples of Community Members Exposed Through Drinking Water (Second Complaint)

According to EPA's Second Complaint, in July 2004 DuPont performed a blood serum analysis on 12 members of the general population living near DuPont's Washington Works Facility in West Virginia.⁴⁴

The Second Complaint states that each of the individuals tested was exposed to PFOA through drinking water provided by the Lubeck Public Service District where, according to DuPont, the level of PFOA in the drinking water averaged approximately 0.5 ppb over the last several years.⁴⁵ All of the individuals tested claim to have stopped using the contaminated public drinking water as their primary source of drinking water approximately three years ago.⁴⁶ The Second Complaint states:

Human serum sample levels of PFOA for these 12 individuals were reported to range from 15.7 ppb to 128 ppb, with a mean of 67 ppb. The median value is in the range of 60 ppb PFOA. . . . [T]he average background serum level of PFOA in individuals residing in the United States is estimated to be approximately 5 ppb.⁴⁷

The Second Complaint further states:

The human serum sampling data 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*. This data is information that reasonably supports the conclusion that PFOA presents a substantial risk of injury to human health that the Administrator was not already adequately informed about at the time the information was obtained by DuPont or at any time prior to the date EPA received the data.

The Agency considers the human serum sampling information to reasonably support the conclusion of a substantial risk of injury to health or the environment [emphasis added].⁴⁸

DuPont filed a formal response to the new complaint on January 7, 2005, denying EPA's legal assertions.⁴⁹ Among other responses, DuPont asserted that there was no "substantial risk" as that term is defined under Section 8(e) and that, in any event, EPA was aware of the information at issue.

Implications of the DuPont Enforcement Actions

The DuPont cases raise important legal issues that could have far-reaching implications for the chemical community and others who are subject to TSCA reporting. EPA is apparently taking the position that information showing an exceedance of a company-set

exposure guideline can be reportable under TSCA Section 8(e), even if the information does not show an exceedance of a government-set exposure standard, and even when small or minor exceedances of government-set standards may generally not be reportable.⁵⁰

The concern that many have expressed with EPA's position is that it could discourage companies from developing internal health and safety standards that are more restrictive than government-established standards.

Similarly, the allegation regarding the placental transfer of PFOA raises new issues regarding traditional interpretations of what constitutes a "significant adverse effect" for purposes of TSCA Section 8(e) reporting, and when information is already known to EPA.

EPA's Second Complaint raises troubling issues concerning the circumstances under which the mere presence of a chemical in human blood might be considered to require a report under Section 8(e), when no effect other than presence has been asserted.

The complaint alleges facts that tie the presence in blood to the defined dose determined in the drinking water of those whose blood samples were at issue, but also contains broader statements that could signal a possible future new approach to determining the reportability of biomonitoring data.

EPA's assertions against DuPont are specifically related to a controversial chemical product. PFOA might have spawned such assertions where another, less controversial, product might not. Nonetheless, the enforcement actions against DuPont are being watched with concern by the chemical industry.

The precedents that potentially may be set in these cases could change the interpretation of what is and is not reportable under Section 8(e). They also could change significantly the product stewardship programs of companies that use voluntary internal standards to go above and beyond what they are required to do by law.

Limitations of EPA's Current Guidance on Genomics

The DuPont case also emphasizes the limitations of EPA's guidance with respect to the legal relevance of genomic data for TSCA reporting purposes.

EPA issued its *Interim Policy on Genomics* in 2002.⁵¹ In it, the Agency encourages and supports continued genomic research, clarifies that genomic data alone are "insufficient as a basis for decisions," and states that changes in gene expression "can be informative when a weight-of-evidence approach for human and ecological health assessments is performed."⁵²

The policy is correctly captioned "interim" -- thus telegraphing to the regulated community EPA's desire for flexibility and timeliness. The *Interim Policy* is nonetheless short on detail with respect to the relevance of genomic data, particularly when read against the backdrop of the DuPont complaints.

Critical to EPA's allegation in the DuPont actions is the question of what constitutes an "adverse effect." Just as no inferences can be drawn from a change in gene expression alone, no inferences properly can be drawn from the mere presence of a chemical in human blood without an associated tie to an adverse effect.

Nonetheless, EPA appears in the Second Complaint to be signaling that it may take precisely this position. While the Second Complaint alleges facts that tie the presence of PFOA in blood to the defined dose determined in the drinking water of those whose blood samples are at issue, it also contains broader statements that could signal a possible future new approach to determining the reportability of biomonitoring data.

In that genomic data are "predictive" of potential toxicity -- and thus one or several steps removed from any finding of adverse effect -- the *Interim Policy* would seem to dictate that no TSCA reporting obligations would arise as a result of the DuPont PFOA data that are the subject of the Second Complaint. No observed toxicological effect (either serious or significant) is alleged in connection with the presence of PFOA in community blood levels, though there are animal study data that indicate possible toxicological effects.

EPA's allegations in the DuPont actions cast doubt on the continued viability of this interpretation of the *Interim Policy*, and raise the question of whether the Agency's policy has in fact shifted.

Time for Better Reporting Guidelines?

EPA's *Interim Policy*, and any newer iterations of it, would benefit from greater clarity on the subject of what kinds of data the Agency believes trigger TSCA Section 8(e) reporting obligations. Better guidance would blunt growing concerns about EPA's evolving legal position in this area, and provide much needed clarity that could reduce the legal and business uncertainties inspired by the DuPont complaints.

In the Genomics Task Force White Paper, EPA correctly notes that

[t]here is a need to interpret how these TSCA and FIFRA provisions apply to genomic data. . . . As the predictability and validity of genomics methods increase, EPA may need to re-evaluate its stance on these reporting provisions. Because these provisions address the reporting of adverse effects, the issue of what genomic changes mean in terms of adversity must be addressed before reporting for genomic responses may be required.⁵³

Some might assert, with considerable merit, that the time to re-evaluate the *Interim Policy on Genomics* is now.

Looking Toward the Future

The universe of genomic data will expand exponentially in the years to come. Regulated entities and regulators alike need to focus fast on what these data mean, how they should and can be used for regulatory purposes, and how all stakeholders can work together to ensure that appropriate guidelines and policies are in place to guarantee the necessary results.

As promising as genomic data are, their value will remain unfulfilled unless there are clear standards on their use, application, and interpretation.

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Notes

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- ¹ The Genomics Task Force White Paper is available at <http://www.epa.gov/OSA/genomics.htm>.
- ² *Id.* at vii.
- ³ The Final Bulletin is available at http://www.whitehouse.gov/omb/inforeg/peer2004/peer_bulletin.pdf.
- ⁴ *Id.* at 7, quoting 44 U.S.C. § 3504(d).
- ⁵ Pub. L. No. 106-554, § 515(a).
- ⁶ See Marchant, G.E. (2003). Genomics and Toxic Substances: Part I -- Toxicogenomics. *Environmental Law Reporter*, 33, 10071-10093. *Cited in* Genomics Task Force White Paper, note 1 above.
- ⁷ Genomics Task Force White Paper, note 1 above, at 11.
- ⁸ 67 Fed. Reg. 8452 (February 22, 2002).
- ⁹ See Office of Management Budget's Agency Information Quality Guidelines, available at http://www.whitehouse.gov/omb/inforeg/agency_info_quality_links.html.
- ¹⁰ Available at http://www.whitehouse.gov/omb/inforeg/peer_review041404.pdf.
- ¹¹ Final Bulletin, note 3 above, at 9.
- ¹² *Id.* at 35.
- ¹³ *Id.* at 40.
- ¹⁴ *Id.* at 10.
- ¹⁵ *Id.*
- ¹⁶ *Id.* at 36.
- ¹⁷ *Id.* at 37-38.
- ¹⁸ Genomics Task Force White Paper, note 1 above, at 4.
- ¹⁹ Final Bulletin, note 3 above, at 8.

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Id.

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US Environmental Protection Agency (2004, July 8). EPA Press Advisory: EPA Takes Enforcement Action Against DuPont For Toxic Substances Reporting Violations.

US Environmental Protection Agency (2004, December 6). EPA Press Advisory: EPA Files New Claim Alleging DuPont Withheld PFOA Information.

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In addition to the TSCA allegations, EPA's initial complaint alleges one violation of the Resource Conservation and Recovery Act (RCRA). EPA alleges that DuPont's failure to submit toxicological information which the company had obtained regarding perfluorooctanoic acid (PFOA) used in the manufacturing process for fluoropolymers at its Washington Works facility in West Virginia violated provisions contained in the company's RCRA Corrective Action Permit. *See* E.I. du Pont de Nemours and Company, TSCA-HQ-2004-0016, RCRA-HQ-2004-0016 (July 8, 2004), available at <http://www.epa.gov/compliance/resources/complaints/civil/mm/dupont-pfoa-complaint.pdf> (First Complaint).

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TSCA § 8(e), 15 U.S.C. § 2607(e).

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68 Fed. Reg. 33129, 33138 (June 3, 2003).

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EPA requirements governing emergency incidents of environmental contamination are not addressed here.

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68 Fed. Reg. at 33138. EPA also identifies four other types of "environmental effects" for which substantial-risk information should be reported, including measurements and indicators of pronounced bioaccumulation, ecologically significant changes in species' interrelationships, and facile transformation or degradation to a chemical having an unacceptable risk. *Id.* Effects related to the environment do not appear applicable to measurements of worker blood or to workplace air concentrations, nor is the author aware of any instance in which EPA has asserted a different conclusion.

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US Environmental Protection Agency (2003, February). Comment and Response Document for Revised Policy Statement of Section 8(e) of TSCA (RTC) at 12, 15:

COMMENT: . . . The proposed language could be simplified while still emphasizing that all four aspects of a possible scenario for section 8(e) reporting must be present, i.e., widespread, previously unsuspected, known serious effects, and actual or high probability of exposure. Proposed text follows: "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.” . . .

RESPONSE: Finally, EPA agrees that the suggested text which embodies the concepts of widespread distribution, previously unsuspected distribution, known significant toxicity, and actual or probable significant exposure, in combination with other unmodified sections of the policy statement, is responsive to the comments.

28 70 Fed. Reg. 2162 (January 12, 2005).

29 The questions and answers (Q&As), which can be found at <http://www.epa.gov/oppt/tsca8e/>, include the following:

Q.1. Analysis of soil or groundwater samples provides new information about the extent of contamination at a site known to be contaminated. Is this information “previously unsuspected”?

A.1. New information about the presence of a substance or mixture in soil or groundwater (or other environmental media) at a site known to be contaminated with that substance or mixture would be “previously unsuspected” if it materially added to or changed the understanding of the amount, extent and/or pattern (e.g., groundwater in addition to previous evidence in soil) of site contamination.

30 First Complaint, note 22 above.

31 E.I. du Pont de Nemours and Company, TSCA-HQ-2004-0016, RCRA-HQ-2004-0016, Answer and Request for Hearing (August 11, 2004), available at http://www1.dupont.com/dupontglobal/corp/documents/US/en_US/news/releases/pdf/answer_and_request_for_hearing.pdf (DuPont Answer).

32 E.I. du Pont de Nemours and Company, TSCA-HQ-2005-5001 (December 6, 2004), Complaint and Notice of Opportunity for Hearing, available at <http://www.epa.gov/compliance/resources/complaints/civil/mm/dupont2-pfoa-complaint.pdf> (Second Complaint).

33 An earlier installment of this column discussed the first enforcement action against DuPont in detail. *See* Bergeson, L.L. (2004, winter). Washington Watch: Internal Guidelines and TSCA: The Implications of EPA’s Case Against DuPont. *Environmental Quality Management*, 14(2), 77-83.

34 First Complaint, note 22 above, at 11.

35 DuPont Answer, note 31 above, at 1.

36 *Id.* at 3.

37 *Id.*

38 *Id.*

39 First Complaint, note 22 above, at 19.

40 DuPont Answer, note 31 above, at 4.

41 *Id.* at 5.

42 *Id.* at 4.

43 *Id.* at 5.

44 Second Complaint, note 32 above, at 6-7.

45 *Id.*

46 *Id.* at 7.

47 *Id.*

48 *Id.* at 7-8.

49 In the Matter of E.I. du Pont de Nemours and Company, TSCA-HQ-2005-5001, Answer
to Complaint and Request for Hearing (January 7, 2005).

50 *See* RTC, note 27 above, at 15.

51 Available at <http://epa.gov/osa/spc/htm/genomics.pdf>

52 *Id.* at 2.

53 Genomics Task Force White Paper, note 1 above, at 15.