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TSCA—Chemical Testing Issues

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This Article introduces the Toxic Substances Control Act (TSCA),[1] and describes chemical substances for which testing could be conducted under TSCA, chemical testing that could be required, persons required to conduct the tests, procedures that have been considered for selecting test chemicals, and associated legal challenges.

I. TSCA

The U.S. Congress enacted TSCA in 1976 to regulate the manufacture, processing, use, transportation, and disposal of certain chemical substances and to protect human health and the environment by requiring testing and use restrictions on these chemical substances.[2] In general, these chemicals do not include substances that are used only as pesticides, tobacco products, nuclear materials, foods, food additives, drugs, cosmetics, and medical devices. TSCA §4 provides the U.S. Environmental Protection Agency (EPA) the authority to promulgate rules requiring manufacturers, importers, and processors to test certain new or existing chemical substances or mixtures for their effects on human health and the environment. These data can be used, in turn, to help EPA, other federal agencies, and state and local governments to determine both whether and how to regulate or control potentially hazardous chemicals. In addition to developing test rules under TSCA §4, EPA also uses enforceable consent agreements (ECAs) and voluntary testing programs, such as the High Production Volume (HPV) Challenge Program and the Voluntary Children's Chemical Evaluation Program (VCCEP), to generate data.

II. Chemical Substances

TSCA regulates chemical substances.[3] TSCA defines the term chemical substance as "any organic or inorganic substance of a particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical."[4] EPA states: "TSCA defines 'chemical substance' broadly and in terms which cover microorganisms as well as traditional chemicals."[5]

TSCA provides several exemptions from the definition of chemical substances: mixtures; Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticides; tobacco and tobacco products; certain materials regulated under the Atomic Energy Act; fire arms and ammunition; and foods, food additives, drugs, cosmetics, and devices regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA).[6] TSCA defines only one of these exemptions—mixture. Under TSCA, a mixture is "any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction."[7] Also included in the definition of a mixture is any chemical substance that is the result of a chemical reaction, but that could have been manufactured for commercial purposes without a reaction. EPA provides as examples of mixtures alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.[8]

Some substances that appear to meet the definition of an exempt substance are nonetheless subject to TSCA requirements. Dual-use chemical substances can be subject to TSCA and another statute. For example, a chemical is subject to FIFRA when used as a pesticide, but subject to TSCA when used as a general solvent. Similarly, even though mixtures, as defined under TSCA, are exempt from the definition of a chemical substance, they are still subject to certain TSCA requirements. In addition, each component of a mixture is considered a chemical substance within the meaning of TSCA.

III. Chemical Testing

Under TSCA §4, EPA can promulgate rules that require manufacturers, including importers, and, in some cases, processors to conduct testing of chemical substances for which EPA makes certain findings. After EPA determines whether the statutory requirements are satisfied, EPA pub-

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1. 15 U.S.C. §§2601-2692, ELR STAT. TSCA §§2-412.
2. Pub. L. No. 94-469, 90 Stat. 2003 et seq. (1976); 15 U.S.C. §§2601 et seq.
3. TSCA §2(b).
4. *Id.* §3(2)(A).
5. 62 Fed. Reg. 17909, 17911 (Apr. 11, 1997) (promulgating final rule under TSCA §5 to establish notification procedures for review of certain new microorganisms).
6. TSCA §3(2)(B).
7. *Id.* §3(8); 40 C.F.R. §712.3(i).
8. 40 C.F.R. §712.3(i).

lishes a TSCA §4 *Federal Register* notice proposing a test rule.[9] Although the bulk of EPA's test rules have been promulgated in response to TSCA Interagency Testing Committee (ITC) designations, EPA program offices also identify candidates for testing. EPA proposed the hazardous air pollutants (HAPs) test rule in furtherance of its statutory obligation to determine human health risks under Clean Air Act (CAA) §112.[10] EPA also has required testing, under TSCA §4, of chemicals referred by its Office of Solid Waste and Office of Water.[11]

A. Selecting Chemicals for Testing

Since 1977, the ITC has been selecting existing chemicals for testing. Congress created the ITC in 1976 under TSCA §4(e) as an independent advisory committee to the EPA Administrator. The ITC was created to identify chemicals regulated by TSCA for which there are suspicions of toxicity or exposure and for which there are few, if any, ecological effects, environmental fate, or health effects testing data. The ITC includes representatives from 16 federal organizations.[12]

Under TSCA §4(e), the ITC must establish the TSCA §4(e) *Priority Testing List* (chemicals or chemical groups recommended to the EPA Administrator for testing), revise the *Priority Testing List* at least every six months, and submit the revisions as ITC Reports to the EPA Administrator.[13] When making recommendations to EPA, the ITC is directed to consider, among other factors: (1) the production volume; (2) the quantities released to the environment; (3) the extent of human exposure; (4) the existing health effects data; (5) the extent to which testing may result in the development of useful data upon which the effects of the substance on health or the environment may be predicted; and (6) the availability of facilities and personnel to conduct testing.[14] TSCA §4(e) mandates that EPA publish the ITC Reports in the *Federal Register* and states that EPA should take actions on the ITC's recommended chemicals or chemical groups by implementing the testing recommendations or reporting to the public why recommendations are not being implemented.[15] Details of the ITC's and EPA's chemical testing activities from 1977 to 1992 have been published.[16] As of November 2002, the ITC had recommended information reporting or testing for approximately 4,200 chemicals and deferred information reporting or testing for approximately 38,000 chemicals.[17] The *Priority Testing List* is available on the Internet, where it may be searched by Chemical Abstracts Service (CAS) Number, chemical name, or ITC Report.[18]

B. Test Rules

Congress enacted TSCA §4 in response to the concern that the effects of chemical substances and mixtures on human health and the environment were insufficiently characterized or understood. One of the stated policies of TSCA is that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should

9. Details of the types, numbers, and rationales for EPA's publication of TSCA §4 *Federal Register* notices from 1980 to 1988 have been published. John D. Walker, *Bioconcentration, Chemical Fate, and Environmental Effects Testing Under Section 4 of the Toxic Substances Control Act*, 5 TOXICITY ASSESSMENT 61-75 (1990); John D. Walker, *Bioconcentration, Chemical Fate, and Aquatic Toxicity Testing Under the Toxic Substances Control Act: Proposed Testing and Decision Criteria*, 5 TOXICITY ASSESSMENT 103-34 (1990). In addition, the types of chemicals, test methods, and data developed from publishing TSCA §4 *Federal Register* notices have also been published. *See* John D. Walker, *Review of Chemical Fate Testing Conducted Under Section 4 of the Toxic Substances Control Act: Chemicals, Tests, and Methods*, *in* AQUATIC TOXICOLOGY AND RISK ASSESSMENT: THIRTEENTH VOLUME 77-90 (Wayne G. Landis and William H. Vanderschaile eds., ASTM 1990); John D. Walker, *Acrylamide Aquatic Effects: Potential Impact of Extended Exposure*, 6 ENVTL. TOXICOLOGY & WATER QUALITY 363-69 (1991); John D. Walker, *Review of Ecological Effects and Bioconcentration Testing Recommended by the TSCA Interagency Testing Committee and Implemented by EPA Under the Toxic Substances Control Act: Chemicals, Tests, and Methods*, *in* ENVIRONMENTAL TOXICOLOGY AND RISK ASSESSMENT 92-115 (Wayne G. Landis et al. eds., ASTM 1993); John D. Walker, *The TSCA Interagency Testing Committee's Role in Facilitating Development of Test Methods: Toxicity and Bioconcentration Testing of Chemicals Added to Sediment*, *in* ENVIRONMENTAL TOXICOLOGY AND RISK ASSESSMENT: SECOND VOLUME 688-722 (Joseph W. Gorsuch et al. eds., ASTM 1993) [hereinafter ENVIRONMENTAL TOXICOLOGY AND RISK ASSESSMENT: SECOND VOLUME]; John D. Walker, *Testing Decisions of the TSCA Interagency Testing Committee for Brominated Flame Retardants: A Review of Decisions and Health and Safety Data*, *in* THE FUTURE OF FIRE-RETARDED MATERIALS: APPLICATIONS AND REGULATION 185-220 (Fire Retardant Chemicals Ass'n 1994); John D. Walker, *Recommendations of the TSCA Interagency Testing Committee: Aquatic Toxicity, Bioconcentration, and Chemical Fate Data Developed Under Section 4 of the Toxic Substances Control Act*, *in* FUNDAMENTALS OF AQUATIC TOXICOLOGY II 669-701 (Gary M. Rand ed., Taylor & Francis Publishers 1995).

10. 61 Fed. Reg. 33178 (June 26, 1996).

11. 53 Fed. Reg. 22300 (June 15, 1988); 58 Fed. Reg. 59667 (Nov. 10, 1993).

12. The organizations include the Agency for Toxic Substances and Disease Registry; Council on Environmental Quality; Consumer Product Safety Commission; U.S. Department of Commerce; U.S. Department of Defense; U.S. Department of the Interior; EPA; Food and Drug Administration; National Cancer Institute; National Institute of Environmental Health Sciences; National Institute for Occupational Safety and Health; National Library of Medicine; National Science Foundation; National Toxicology Program; Occupational Safety and Health Administration; and U.S. Department of Agriculture. *See* U.S. EPA, *ITC Member Organizations*, *at* http://www.epa.gov/opptintr/itc/mbrorgs.htm (last updated Apr. 13, 2004).

13. TSCA §4(e)(1)(B). The ITC revises the *Priority Testing List* every May and November. *See* U.S. EPA, *Frequently Asked Questions (FAQs): Welcome to the ITC's Public Information Access Page*, *at* http://www.epa.gov/opptintr/itc/faq.htm (last updated Nov. 7, 2002) [hereinafter U.S. EPA, *FAQs*].

14. TSCA §4(e)(1)(A).

15. *Id.* §4(e)(1)(B). The most recent ITC Report was published on June 15, 2004. 69 Fed. Reg. 33528 (June 15, 2004). The ITC Reports are available on the Internet at http://tsca-itc.syrres.com/Reports/ (last visited Sept. 15, 2004). In 1980, in *Natural Resources Defense Council v. Costle*, the Natural Resources Defense Council, Inc. (NRDC) filed suit against EPA for not providing adequate responses to ITC's first and second Reports, which designated 18 substances as high priority for health and environmental effects testing. The court found that generalizations on EPA's difficulties "do[ ] not fulfill the Congressional requirement that the EPA provide 'reasons' for not initiating rulemaking proceedings with respect to the [ITC's] designated 'priority' chemicals." The court granted NRDC's motion for partial summary judgment and ordered EPA to submit its proposed plans for compliance. Natural Resources Defense Council v. Costle, No. 79 Civ. 2411, 1980 U.S. Dist. LEXIS 17298, 10 ELR 20274 (S.D.N.Y. 1980).

16. John D. Walker, *The TSCA Interagency Testing Committee, 1997-1992: Creation, Structure, Functions, and Contributions*, *in* ENVIRONMENTAL TOXICOLOGY AND RISK ASSESSMENT: SECOND VOLUME, *supra* note 9, at 451-509.

17. U.S. EPA, *FAQs*, *supra* note 13.

18. U.S. EPA, *ITC Priority Testing List*, *at* http://tsca-itc.syrres.com/Chemicals/ (last visited Sept. 15, 2004).

be the responsibility of those who manufacture and those who process such chemical substances and mixtures."[19] TSCA §4 gives EPA broad authority to require the development of adequate test data on the ecological effects, environmental fate, and health effects of such substances. Under TSCA §4, EPA can require manufacturers, including importers, and, in some cases, processors to conduct testing of chemical substances for which EPA makes certain findings.

EPA may issue test rules either under TSCA §4(a), based on a hazard finding, or under TSCA §4(b), based on an exposure finding. TSCA §4(a) states that, to require testing, EPA must find that "the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment."[20] Under TSCA §4(b), EPA must find that a chemical substance or mixture is or will be produced in substantial quantities and that either "it enters or may reasonably be anticipated to enter the environment in substantial quantities" or "there is or may be significant or substantial human exposure to such substance or mixture."[21] Both sections require that EPA show that existing data are inadequate for risk assessment and that testing is needed to develop the data necessary to conduct the needed risk assessment.[22] To date, EPA has promulgated test rules addressing approximately 120 chemicals and published formal "Decisions Not to Test" for another 250 chemicals.[23]

There has been considerable litigation regarding what constitutes an "unreasonable risk" under TSCA. Courts have upheld EPA's test rules where, for example, EPA's basis for suspecting the existence of an unreasonable risk of injury to health is "substantial," that is, when there is a more than theoretical basis for suspecting that some amount of exposure occurs, and that the substance is sufficiently toxic at that exposure level to present an unreasonable risk of injury to health.[24] In 1988, in *Ausimont U.S.A. Inc. v. U.S. Environmental Protection Agency*,[25] manufacturers challenged EPA's final test rule for fluoroalkenes. The manufacturers argued that, before issuing a test rule, "EPA must demonstrate that humans are actually exposed to the chemicals to such a degree that serious harm could result if the substances are toxic."[26] EPA responded that it can issue a TSCA test rule "based on potential exposure" and that "scientific uncertainty over the possible harmful effects of the chemicals provides the justification for testing."[27] The U.S. Court of Appeals for the Third Circuit upheld EPA's final test rule, stating that while TSCA "prevents a testing rule based on little more than scientific curiosity," EPA can act when "an existing possibility of harm raises reasonable and legitimate cause for concern."[28]

In 1988, the U.S. Court of Appeals for the District of Columbia (D.C.) Circuit found that *Chemical Manufacturers Ass'n v. U.S. Environmental Protection Agency*[29] presented three issues: whether EPA must find that the existence of an "unreasonable risk of injury to health" is more probable than not; whether EPA must rebut industry evidence tending to show an absence of human exposure by producing direct evidence of exposure; and whether EPA has the authority to issue a test rule where any individual's exposure to a substance "is an isolated, non-recurrent event."[30] On each issue, the court found that Congress did not address the precise question and that EPA's construction of TSCA in resolving the question was reasonable:

> [W]e uphold EPA's conclusion that it is empowered to issue a test rule where the evidence pointing to the presence of an "unreasonable risk of injury to health" is substantial enough to indicate that the decision to issue a test rule is based on more than theory, speculation and conjecture. The Agency must find that there is a more-than-theoretical basis for concluding that some amount of exposure takes place and that toxicity at that level of exposure suffices to present an "unreasonable risk of injury to health." Inferences drawn from the circumstances under which a substance is manufactured and used can suffice to establish the existence and amount of exposure. Industry-supplied evidence attacking those inferences must be rebutted by EPA only if the industry evidence renders the probability of exposure at a level sufficient to present an unreasonable risk no more than theoretical and speculative. So long as there is a more-than-theoretical probability that the toxic substance in rare or single doses presents an "unreasonable risk of injury to health," the statutory standard is met whatever the infrequency of exposure.[31]

In 1990, manufacturers challenged a final TSCA §4 test rule on cumene, arguing that EPA did not articulate any clear basis for its determinations that the quantities of cumene that enter the environment are "substantial" and that the potentially resulting human exposure to cumene is also "substantial."[32] The court agreed and remanded the rule back to EPA to articulate the criteria used to make "B" findings. In response, EPA established the following criteria that form the basis for EPA's policy for making B-based findings:

- Substantial production/importation (1 million pounds) and;
- Substantial release (1 million pounds or 10% of production/importation) or;
- Substantial human exposure (1,000 workers or 10,000 consumers or 100,000 general population) or;
- Significant human exposure (determined on a case-by-case basis).[33]

Under the B policy, EPA will make findings of substantial

19. TSCA §2(b)(1).
20. *Id.* §4(a)(1)(A)(i).
21. *Id.* §4(a)(1)(B)(i).
22. *Id.* §§4(a)(1)(A)(ii)-(iii), 4(a)(1)(B)(ii)-(iii).
23. Greg Schweer, Chief, Chemical Information and Testing Branch, Office of Pollution Prevention and Toxics, EPA, Overview of TSCA Chemical Testing (Data Development) Activities (Mar. 2004) at slide 8, presented at the Global Chemical Regulations Conference, *available at* http://www.socma.com/PDFfiles/gcrc_04/presentations/Schweer.pdf (last visited Sept. 8, 2004).
24. Chemical Mfrs. Ass'n v. EPA, 859 F.2d 977, 19 ELR 20001 (D.C. Cir. 1988).
25. 838 F.2d 93, 18 ELR 20456 (3d Cir. 1988).
26. *Id*. at 95.
27. *Id*.
28. *Id*. at 97.
29. 859 F.2d 977, 19 ELR 20001 (D.C. Cir. 1988).
30. *Id.* at 983-84.
31. *Id*. at 990-91.
32. Chemical Mfrs. Ass'n v. EPA, 899 F.2d 344, 20 ELR 20837 (5th Cir. 1990).
33. 58 Fed. Reg. 28736 (May 14, 1993).

production where substances are produced in quantities of one million pounds or more annually. Even when the size of a potentially exposed population does not exceed the thresholds listed above, EPA may make the requisite findings based on significant human exposure when the nature of exposure occurs more directly than that which usually characterizes such exposure. Additionally, in defining the phrase "enters the environment in substantial quantities," EPA stated that it would make the requisite finding whenever a chemical has been released to the environment in quantities equal to at least 10 % of its total production, or one million pounds per year, whichever is lower.

The basis upon which EPA has made its so-called B findings has been the subject of considerable debate. Industry often alleges that EPA's factual support for its "substantial human exposure" allegations are outdated and flawed.

Since 1991, EPA has proposed four significant test rules, only one of which has been issued in final: the reproductive/developmental multisubstance endpoint rule; the HAP test rule; the dermal testing rule, which was issued in final in April 2004; and the HPV test rule:

- Reproductive/Developmental Multisubstance Endpoint Rule—In 1991, EPA proposed developmental and/or reproductive toxicity testing for 10 chemicals.[34] The proposal, which has yet to be issued as a final rule, is one of several TSCA §4 proposals aimed at compelling the production of health effects data on a particular health endpoint for multiple chemical substances. EPA proposed comprehensive and costly tests to assess the reproductive and/or developmental toxicity of the designated chemicals.
- HAP Test Rule—In 1996, EPA proposed testing for 21 HAPs to help EPA conduct residual risk assessments under the CAA.[35] Compounds were selected primarily based on their release to air as reported under §313 of the Emergency Planning and Community Right-To-Know Act (EPCRA). All chemicals selected for inclusion in the test rule had reported air emissions in excess of 50 tons in 1993. EPA has not yet issued this rule in final. Several of the substances listed in the 1996 rule have become the subject of ECAs.[36]
- Dermal Testing Rule—In 1999, EPA proposed *in vitro* dermal absorption testing for 47 HPV industrial chemicals.[37] On April 26, 2004, EPA issued a final dermal testing rule for 34 chemicals.[38] The Occupational Safety and Health Administration identified the data necessary for these chemicals and intends to use the data obtained under the rule to evaluate the need for skin designations to alert employers, industrial hygienists, and workers to potential exposure to a chemical via absorption through the skin. The final rule covers significantly more entities than previous TSCA test rules.
- HPV Test Rule—In 2000, EPA proposed testing for 37 HPV substances.[39] The proposed tests included acute toxicity; repeat dose toxicity; developmental and reproductive toxicity; genetic toxicity (gene mutations and chromosomal aberrations); ecotoxicity (in fish, *Daphnia*, and algae); and environmental fate (including five tests for physical chemical properties and biodegradation). EPA stated that it "has preliminarily determined that each of the 37 chemical substances included in this proposed rule is produced in substantial quantities and that there is substantial human exposure to each of them."[40]

C. ECAs

EPA has determined that it has implied authority to enter into ECAs when such agreements provide procedural safeguards equivalent to those that apply when chemical testing is conducted by rule.[41] EPA often prefers such agreements because they avoid the costs and lengthy delays associated with TSCA notice-and-comment rulemaking. Manufacturers often favor ECAs because EPA regulations permit them to become involved at an early phase and potentially influence EPA's preliminary testing determinations. Approximately 60 chemicals are currently subject to negotiated testing agreements and/or ECAs.[42]

ECAs require consensus among EPA, affected manufacturers and/or processors, and any other persons who have asked to participate in or monitor negotiations.[43] EPA will not enter into a consent agreement in either of the following circumstances: (1) EPA and affected manufacturers and/or processors cannot reach a consensus on the testing requirements or other provisions to be included in the ECA; or (2) a draft ECA is considered inadequate by other interested parties who have asked to participate in or monitor negotiations, and these parties have submitted timely written objections to the draft consent agreement that provide a specific explanation of the grounds on which the draft agreement is objectionable.[44] Under the regulations, EPA may reject objections only where it concludes the objections meet one of the following criteria:

- The objection is not made in good faith;
- The objection is untimely;
- The objection does not involve the adequacy of the proposed testing program or other features of the agreement that may affect EPA's ability to fulfill the goals and purposes of TSCA; or
- The objection is not accompanied by a specific explanation of the grounds on which the draft agreement is considered objectionable.[45]

34. 56 Fed. Reg. 9092 (Mar. 4, 1991).

35. 61 Fed. Reg. at 33178, as amended at 62 Fed Reg. 67466 (Dec. 24, 1997) and 63 Fed Reg. 19694 (Apr. 21, 1998).

36. *See* 62 Fed. Reg. 2607 (Jan. 17, 1997) (final ECA and testing consent order for phenol); 64 Red. Reg. 20298 (Apr. 26, 1999) (final ECA and testing consent order for methyl isobutyl ketone); 65 Fed. Reg. 37550 (June 15, 2000) (final ECA and testing consent order for 1,1,2-trichloroethane); and 68 Fed. Reg. 33125 (June 3, 2003) (final ECA and testing consent order for 1,2-ethylene dichloride).

37. 64 Fed. Reg. 31074 (June 9, 1999).

38. 69 Fed. Reg. 22402 (Apr. 26, 2004).

39. 65 Fed. Reg. 81658 (Dec. 26, 2000).

40. *Id.*

41. 40 C.F.R. §790.1(b).

42. Overview of TSCA Chemical Testing (Data Development) Activities at slide 8, *supra* note 23.

43. 40 C.F.R. §790.28(c).

44. *Id.* §790.24(a).

45. *Id.* §790.24(b).

The regulations state that the unwillingness of some manufacturers and/or processors of a prospective test chemical to sign the ECA does not, in itself, establish a lack of consensus if EPA concludes that those manufacturers and/or processors who are prepared to sign the agreement are capable of accomplishing the testing to be required and that the draft agreement will achieve the purposes of TSCA in all other respects.[46]

To enter an ECA, EPA is not required to make findings that there are insufficient data and testing is necessary to develop such data, and manufacturers, importers, and processors have no opportunity to challenge the testing requirements. The legal obligations of an ECA apply only to persons who sign the ECA, while TSCA §4 test rules apply to all manufacturers, importers, and processors. ECAs do not provide a right to reimbursement from any other party, unlike TSCA §4 test rules. ECAs and TSCA §4 test rules do have several similarities:

- Test standards often are similar;
- Testing typically by consortia;
- Study plans must be submitted to EPA[47];
- Good Laboratory Practice (GLP) requirements[48];
- Interim reports[49];
- Final reports[50];
- Procedures for modifying test plans[51];
- Export notification requirements; and
- Penalties for noncompliance.[52]

From EPA's perspective, obtaining data through an ECA may provide the best opportunity to negotiate the most scientifically appropriate testing requirements. The ECA process often allows for more creative approaches to testing and also allows EPA to consider "agreed-upon pollution prevention and other types of product stewardship initiatives by the chemical industry as a possible substitute for or adjunct to certain types of needed testing."[53] Usually the ECA negotiation process is less expensive than engaging in rulemaking, although it is not necessarily faster and the result is that testing is always required. TSCA notice-and-comment rulemaking is expensive, particularly where the final rule is judicially challenged. Data development requirements, however, are far less certain.

On April 16, 2003, EPA initiated the process to develop one or more ECAs for perfluorooctanoic acid (PFOA) and fluorinated telomers that may metabolize or degrade to PFOA.[54] The first plenary meeting was held on June 6, 2003, and meetings continue to this date.[55] EPA, manufacturers, other federal agencies such as the Consumer Product Safety Commission and the Food and Drug Administration, and environmental groups continue to work toward consensus on various testing proposals. EPA stated at the beginning of the PFOA ECA process that "[t]est rules can take up to two years to complete, while typical ECAs can often be concluded in less than a year."[56] While the PFOA ECA process may have proved more complicated than EPA anticipated, due to the complexity of the testing issues, EPA's statement that test rules can take up to two years to complete underestimates the time taken to promulgate more recent test rules. As noted above, of the four significant test rules proposed since 1991, to date EPA has issued only one in final. The dermal test rule was issued as a proposed rule on June 9, 1999,[57] and was promulgated as a final rule on April 26, 2004.[58]

D. Voluntary Testing

In the early 1980s, EPA used voluntary testing agreements to meet the statutory requirement to respond to ITC designations within 12 months. In 1984, a federal district court ruled that use of voluntary testing agreements was unlawful because it did not comport with requirements to conduct testing "by rule."[59] In response, EPA developed procedures for negotiating ECAs that allow all interested parties to participate and require testing to be conducted in a manner similar to test rules, and EPA stopped using voluntary testing agreements. More recently, however, EPA has developed voluntary testing programs, such as the HPV Challenge Program and VCCEP. In both cases, EPA made it clear that it would issue a TSCA §4 test rule if there were no volunteers to test particular substances. Given the threat of a test rule, many companies chose to participate in the HPV Challenge Program and VCCEP.

Unlike ECAs, voluntary testing programs are not legally enforceable. The programs are voluntary and affect only companies who volunteer. There is no right to reimbursement from other parties, and many companies choose to use data development consortia to share the cost of testing. Other TSCA test rule requirements also do not apply, including procedures for modifications to testing and penalties for noncompliance. Since EPA uses voluntary testing programs to obtain data instead of issuing a test rule, EPA may impose similar test standards. As under ECAs, studies must meet GLP requirements, and reporting requirements may be similar. Excluding the HPV Challenge Program and VCCEP, over 60 chemicals have been or are being tested on a voluntary basis.[60] According to EPA, most voluntary testing actions were initiated by industry as the result of a proposed testing action or concern expressed by EPA.[61]

E. HPV Challenge Program

In 1997 and 1998, recognizing that relatively few TSCA §4

46. *Id.* §790.24(c).
47. *Id.* §§790.50, 790.62.
48. *Id.* §§790.40(b)(1)(v), 790.60(a)(7).
49. *Id.* §§790.50(c)(1)(iv), 790.60(a)(8).
50. *Id.*
51. *Id.* §§790.55, 790.68.
52. *Id.* §§790.59, 790.65.
53. U.S. EPA, *Data Development (Testing)*, *at* http://www.epa.gov/opptintr/chemtest/data.htm (last updated Sept. 22, 2004).
54. 68 Fed. Reg. 18626 (Apr. 16, 2003).
55. The list of meetings is available on the Internet at http://www.epa.gov/opptintr/pfoa/meetings.htm (last updated Oct. 14, 2004).
56. U.S. EPA, OPPT Fact Sheet: PFOA Qs and As (2003), *available at* http://www.epa.gov/opptintr/pfoa/pfoafcts.pdf.
57. 64 Fed. Reg. at 31074.
58. 69 Fed. Reg. at 22402.
59. Natural Resources Defense Council v. EPA, 595 F. Supp. 1255, 14 ELR 20819 (S.D.N.Y. 1984).
60. Overview of TSCA Chemical Testing (Data Development) Activities at slide 8, *supra* note 23.
61. *Id.*

test rules or ECAs have been issued, Environmental Defense (then the Environmental Defense Fund (EDF)), EPA, and the American Chemistry Council (then the Chemical Manufacturers Association (CMA)) conducted reviews to identify issues relating to the development and dissemination of data. The reports generated by these groups confirmed that toxicity data were not publicly available for a majority of the approximately 2,800 HPV chemicals manufactured or imported in the United States.[62] In response to these findings, and with the cooperation of the CMA, EPA created its HPV Challenge Program to encourage chemical manufacturers and importers to conduct testing of chemicals on EPA's list of HPV chemicals, as compiled under the 1990 TSCA Inventory Update Rule (IUR).[63] HPV chemicals are defined as those manufactured or imported in quantities exceeding one million pounds.[64]

HPV testing is intended to generate basic toxicity information as defined by the Organization for Economic Cooperation and Development's (OECD) Screening Information Data Set (SIDS) Program. The SIDS Program requires information on basic physical/chemical properties, and approximately 13 studies in the areas of ecotoxicity, environmental fate, and mammalian toxicity. All data produced under the HPV Challenge Program will be made available to the public.[65] EPA will establish and maintain an electronic database to present the data and information in a meaningful and accurate way. For chemicals that are not sponsored under the HPV Challenge Program, EPA intends to use its TSCA §4 rulemaking authority to compel testing.

There have been a number of challenges to EPA's HPV Challenge Program, and to date, all cases have been dismissed. On May 30, 2000, a coalition of animal rights groups filed suit in the U.S. District Court for the District of Colorado, asking the court to compel EPA to issue a TSCA §8(a) rule to gather basic use and exposure data, and a TSCA §8(d) rule to gather unpublished health and safety data held by companies for any of the 2,800 HPV chemicals targeted for testing under the HPV Challenge Program.[66] The court dismissed the lawsuit in December 2001.

On September 5, 2002, a similar coalition filed suit in the U.S. District Court for the Southern District of New York, claiming that EPA violated the procedural requirements of both TSCA and the Federal Advisory Committee Act (FACA).[67] According to the coalition, EPA violated TSCA by implementing a voluntary testing program rather than promulgating a formal test rule and violated FACA by meeting with CMA and EDF as part of the process of developing and implementing the HPV Challenge Program. On August 25, 2003, the court dismissed the petitioners' motion for summary judgment. The court denied EPA's motion for summary judgment in part and granted it in part. The court found that while there was insufficient evidence in the record to indicate that the necessary TSCA §4 findings have been made, the evidence, when viewed in the light most favorable to the coalition, "suggests that further development of the record might show that, in situations where EPA does not object to testing and HPV Challenge Program testing is allowed to go forward, EPA has implicitly made all of the requisite §4 findings."[68] The court granted EPA's motion for summary judgment with respect to the coalition's FACA claim, finding that "a rational factfinder could not conclude that EPA exerted the level of management or control over the dealings of CMA and EDF that is required for those dealings to fall under the rubric of 'advisory committee' within the meaning of FACA."[69]

On August 18, 2004, the court decided the second round of summary judgment cross-motions, and dismissed the case.[70] The only issue before the court was whether EPA had made, de facto, §4 findings of substantial release and/or substantial exposure with respect to those chemicals for which it did not object to testing. The court concluded that EPA did not make the requisite findings, either with respect to the entire universe of HPV Challenge Program chemicals, or with respect to any subset. The court denied the coalition's second motion for summary judgment and granted EPA's cross-motion for summary judgment.

F. VCCEP

In 1993, the National Academy of Sciences (NAS) published a study entitled *Pesticides in the Diets of Infants and Children*, which noted that pesticide risk assessments may not adequately take children into account when evaluating human health hazards associated with exposure to agricultural chemicals.[71] The study received substantial attention from state and federal regulators, as well as international bodies, and raised questions about the adequacy of environmental laws to protect children's health. On April 21, 1997, former President William J. Clinton signed Executive Order No. 13045, entitled "Protection of Children From Environmental Health Risks and Safety Risks."[72] The Executive Order requires federal agencies to assign a "high priority" to addressing health and safety risks to children, to coordinate research priorities on children's health issues, and to ensure that regulatory standards reflect special risks to children. To implement the Executive Order, then EPA Administrator Carol Browner established the Office of Children's Health Protection in May 1997, to facilitate EPA's efforts to protect children from environmental health threats.

In his April 1998 Earth Day remarks, Vice President Al

62. David Roe et al., Toxic Ignorance (1997), *available at* http://www.environmentaldefense.org/documents/243_toxicignorance.pdf (last visited Sept. 13, 2004); U.S. EPA, Chemical Hazard Data Availability Study (1998), *available at* http://www.epa.gov/chemrtk/hazchem.pdf (last visited Sept. 13, 2004); CMA, Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals (1998).

63. 65 Fed. Reg. 81686, 81689 (Dec. 26, 2000).

64. *Id*. at 81689.

65. Robust summaries and test plans are available on the Internet at http://www.epa.gov/chemrtk/hpvrstp.htm (last updated Oct. 1, 2004).

66. People for the Ethical Treatment of Animals v. Browner, No. 00-D-1090 (D. Colo. filed May 30, 2000). The coalition brought suit after EPA denied a December 27, 1999, petition filed under TSCA §21 to compel rulemaking proceedings for all chemicals included in the HPV Challenge Program. 65 Fed. Reg. 18097 (Apr. 6, 2000).

67. Physicians Comm. for Responsible Med. v. Horinko, 285 F. Supp. 2d 430 (S.D.N.Y. 2003).

68. *Id*. at 441.

69. *Id*. at 447.

70. Physicians Comm. for Responsible Med. v. Leavitt, 331 F. Supp. 2d 204 (S.D.N.Y. 2004).

71. Committee on Pesticides in the Diets of Infants and Children, National Research Council, Pesticides in the Diets of Infants and Children (1993) *available at* http://www.nap.edu/books/0309048753/html/ (last visited Oct. 4, 2004).

72. 62 Fed. Reg. 19883 (Apr. 23, 1997).

Gore gave further expression to the Administration's commitment to children's health issues, announcing a new testing initiative focusing on chemicals children are most likely to encounter. In December 2000, EPA began a pilot study of the VCCEP.[73] The goal of VCCEP is to provide data enabling a better public understanding of the potential health risks to children associated with certain chemical exposures. EPA began the pilot study by asking companies that manufacture or import 23 chemicals found in human tissues and the environment to sponsor an evaluation of these chemicals. Industry sponsors have volunteered for 20 of the 23 chemicals.[74] Sponsorship requires the companies to collect or develop health effects and exposure information on their chemical(s) and then to integrate that information in a risk assessment and a "data needs" assessment.

IV. Persons Required to Test

TSCA §4 provides that only persons who "manufacture" and/or "process" may be subject to TSCA §4 test rules. TSCA §3 defines manufacture as "to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture."[75] EPA's TSCA regulations define the term "manufacture" for other purposes, however. For example, for purposes of TSCA §8(a) general reporting and recordkeeping provisions, EPA defines manufacture as "to manufacture for commercial purposes,"[76] which includes manufacturing for commercial distribution or use in product research and development, as well as byproducts and impurities that are produced coincidentally.[77]

Thus, under EPA regulations, a person will be deemed to "manufacture" a test rule substance—and hence be subject to TSCA §4 testing—even if the test rule substance has no commercial value, if the person manufactures, produces, or imports the test rule substance for commercial advantage or for internal use; imports the test rule substance; or produces the test rule substance "coincidentally during the manufacture, processing, use, or disposal of another substance or mixture." As a result, persons can be subject to a test rule if they produce the test rule substance as a byproduct that is separated from another substance or mixture or as an impurity that remains in another substance or mixture.

The class of persons required to test under the final dermal absorption rate test rule differs from both EPA's reproposed HAP test rule and its earlier test rules. Care must be taken to identify clearly who is required to conduct chemical testing, and assess what arguments, if any, can be made to narrow the scope of the class of persons required to test. This exercise also involves analyzing carefully the test substance to ensure that it is not among the categories of substances for which chemical testing is not required. This discussion regarding how EPA has defined persons required to test is intended only to provide examples of how EPA has defined it in recent test rules. Whether EPA will use one of these approaches in future test rules remains to be seen.

In the 1996 proposed HAP test rule, EPA proposed that "persons who manufacture (including import) or process, or who intend to manufacture or process" a test rule substance, "other than as an impurity, at any time from the effective date of the final test rule to the end of the reimbursement period" would be subject to the testing requirements.[78] These definitions and the scope of coverage of the proposed rule sparked much debate and controversy. Since that time, EPA has sought to revise significantly the categories of persons required to test in the HAP test rule, and has also used different definitions in other proposed test rules. In 1998, EPA issued an amended proposed HAP test rule, in part to clarify the persons required to test.[79] Under the 1998 proposed rule, the class of persons required to test includes:

> Any person who, during the last complete calendar year prior to the publication of the final rule in the *Federal Register*, and any person who, in any successive complete calendar year prior to the end of the reimbursement period, manufactures (including imports) at a particular facility any of the HAPs chemicals included in the first amended proposed rule in an amount of 25,000 lbs or more (regardless of the form of the HAP chemical, *e.g.*, as a Class 1 substance, as a component of a mixture, as a byproduct, as an impurity, as a component of a Class 2 substance, or as an isolated intermediate).[80]

A Class 1 substance is a chemical substance with a composition that can be represented by a specific, complete chemical structure diagram.[81] A Class 2 substance is a complex combination of substances that cannot be represented by a specific, complete chemical structure diagram.[82] In determining the product poundage, the presence of the test rule substance in a mixture at a concentration of less than 1% would not be taken into account. Persons who manufacture or import less than 25,000 pounds per year of the test rule substance, processors, small quantity research and development manufacturers, and manufacturers of the test substance as a component of another chemical substance or mixture, at a concentration of less than 1%, would be conditionally subject to the test rule.[83] They would have to comply with the test requirements only if so directed by EPA because no manufacturer in the class of persons initially subject to the test rule submitted a notice of intent to conduct testing. The category of persons conditionally subject to the HAP test rule would have to provide reimbursement to the persons conducting the testing, in accordance with the test-cost reimbursement provisions. Manufacturers of the test rule substance as a component of a naturally occurring substance or a nonisolated intermediate would be exempt from the test rule, and, accordingly, from the test-cost reimbursement provisions.[84]

EPA's final dermal absorption rate test rule sets up a two-tiered approach for persons subject to the rule, and subjects

73. 65 Fed. Reg. at 81699.
74. U.S. EPA, *VCCEP Pilot Chemicals and Their Sponsors*, *at* http://www.epa.gov/chemrtk/vccep/vcceprsp.htm (last updated Aug. 23, 2002).
75. TSCA §3(7).
76. 40 C.F.R. §704.3.
77. *Id*.
78. 61 Fed. Reg. at 33189.
79. 63 Fed. Reg. at 19694.
80. *Id*. at 19696.
81. 40 C.F.R. §720.45(a)(1)(i).
82. *Id.*
83. 63 Fed. Reg. at 19696.
84. *Id*.

each of these tiers to different regulatory obligations. The Tier 1 class of persons initially required to comply with the test rule includes persons that manufacture (as defined at TSCA §3(7)), or intend to manufacture, in amounts of 500 kilograms (kg), or 1,100 pounds annually, a test rule substance and "who are not listed under Tier 2."[85] The "intent to manufacture" time period runs from the effective date of the final test rule to the end of the test-cost reimbursement period.[86]

Tier 2 is subdivided into Tiers 2A and 2B. Under the final rule, if EPA needs testing from persons in Tier 2, "EPA will seek testing from persons in Tier 2A before proceeding to Tier 2B." EPA states:

> It is appropriate to require manufacturers in Tier 2A to submit letters of intent to test or exemption applications before processors are called upon because the Agency believes that testing costs are traditionally passed by manufacturers along to processors, enabling them to share in the costs of testing (Ref. 74, p. 20654). In addition, "[t]here are [typically] so many processors [of a given test rule chemical] that it would be difficult to include them all in the technical decisions about the tests and in the financial decisions about how to allocate the costs" (Ref. 79, p. 31789).[87]

Tier 2A includes persons who: (1) manufacture or intend to manufacture a test rule substance solely as a byproduct, an impurity, a naturally occurring substance, a nonisolated intermediate, a component of a Class 2 substance as described by 40 C.F.R. §720.45(a)(1)(i), in amounts of less than 500 kg (1,100 pounds) annually as described in 40 C.F.R. §790.42(a)(4), and/or in small quantities solely for research and development.[88] Tier 2B includes persons who process or intend to process a test rule substance.[89]

A manufacturer or processor is not subject to the rule if it does not know, or cannot reasonably ascertain, that it manufactures or processes a listed test substance "(based on all information in your possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without an unreasonable burden)."[90] A Tier 1 person who believes that the required testing may be performed by another person, or a consortium of persons, could apply for an exemption from the required testing. All Tier 2 persons, and Tier 1 persons granted exemptions, are subject to EPA's test-cost reimbursement provisions.[91]

V. TSCA's Cost Reimbursement Provisions

Of great concern to TSCA §4 "manufacturers" is how companies and/or consortia that agree to sponsor chemicals voluntarily should allocate costs incurred when conducting testing. EPA has not addressed this issue. Since a potential test rule is the hammer EPA uses to encourage volunteers, test-cost reimbursement provisions are relevant to those considering whether to volunteer, for the same reasons the "persons required to test" provisions are relevant. In its regulations, EPA sets forth procedures for persons who may be subject to TSCA §4 test rules and who seek assistance in determining the amount or method of reimbursement. As noted above, EPA states in the final dermal test rule that all Tier 2 persons, and Tier 1 persons granted exemptions, are subject to EPA's test-cost reimbursement provisions.[92] These procedures include an opportunity for a hearing with the American Arbitration Association (AAA); publication by EPA of a *Federal Register* document concerning the request for a hearing; and the appointment of a hearing officer to propose an order for fair and equitable reimbursement.[93] The hearing officer may base his or her proposed order on EPA's production volume formula set forth in the regulations.[94]

Under the production volume formula, each person's share of the test cost is in proportion to its share of the total production volume of the test chemical. Production volume is measured over a period that "begins one calendar year before publication of the final test rule in the *Federal Register* and continues up to the latest data available upon resolution of a dispute."[95] Under EPA's regulations, production volume includes amounts imported in bulk form, used in mixtures, and produced as a byproduct.[96] Production volume does not include impurities, unless the test rule specifically includes them, or amounts manufactured for export, unless covered by a finding under TSCA §12.[97] In the final dermal test rule, EPA included in production volume those amounts manufactured as impurities, subject to the discretion of the hearing officer.[98]

TSCA's data reimbursement provisions have been employed rarely, if at all. In the final dermal test rule, EPA notes that in the past, "persons subject to test rules have independently worked out among themselves their respective financial contributions to those persons who have actually conducted the testing."[99] EPA also provides that the regulations "take effect only when private efforts to resolve a dispute have failed and a manufacturer or processor requests EPA's assistance."[100]

VI. Conclusion

Issuing TSCA §4 test rules has proven to be exceedingly time-consuming, resource-intensive, and costly. EPA and industry stakeholders have incurred substantial transaction costs litigating §4 test rules. The strain on resources in no small part results from the complexity of the issues that many test rules pose. For example, for the 1996 proposed HAP test rule, EPA extended the comment period five times due to the complexity of the issues raised by various proposals and the need for more time to issue in final various test guidelines. EPA received hundreds of comments on virtu-

85. 69 Fed. Reg. at 22426.
86. *Id*. at 22425.
87. *Id*. at 22426 (references deleted).
88. *Id*.
89. *Id*.
90. *Id*. at 22425.
91. *Id*.
92. *Id*.
93. 40 C.F.R. §§791.20, 791.22, and 791.29.
94. *Id.* §791.48.
95. *Id.* §791.48(a).
96. *Id.* §791.48(b).
97. *Id.* §791.48(b), (c).
98. 69 Fed. Reg. at 22427.
98. *Id*.
100. 40 C.F.R. §791.2(b).

ally all aspects of the proposed rule, which, by its very name, raised technically complex and legally challenging issues. To date, however, no final rule has been issued, in part because EPA continues to negotiate ECAs with those who would otherwise be subject to the test rule.

Technological and scientific advances have greatly accelerated the distribution of test results and the presentation of those results, and hastened the interpretation of those results. These advances have made possible collaborative testing initiatives such as the HPV Challenge Program. These initiatives have lessened the need for mandatory §4 rulemaking, enhanced stakeholder involvement, and minimized opportunities for government and private sector testing redundancy and inefficiency. At the same time, the very possibility of mandatory §4 rulemaking has contributed to the success of voluntary programs. In this regard, TSCA itself has provided a strong incentive to participate in a voluntary testing initiative that is not itself a product of TSCA.