Chemical Testing Under TSCA—Who Is On the Hook?

by
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Manufacturers of chemical products and products that contain significant chemical components need to be aware of subtle but important changes in the “persons required to test” provisions of Section 4 of the Toxic Substances Control Act (TSCA). Historically, those persons have included chemical manufacturers, processors, or those who intend to process or manufacture a Section 4 test rule substance. In the recent past, the United States Environmental Protection Agency (EPA) has sought to expand the class of persons required to test to include persons whose actions result in the release of the test rule substance into the environment, thus enhancing opportunities for chemical exposure.

EPA’s evolving policy has potentially enormous implications for a diverse range of business entities. The significance of these changes should not be overlooked. Many more businesses could be required to bear the cost of potentially significant TSCA Section 4 testing requirements. This article discusses EPA’s historic Section 4 test standard, reviews EPA’s more recent interpretations of the controlling rules, and discusses the importance of these changes for affected U.S. businesses.

Conceptual Framework

Before reviewing EPA’s historic and evolving standard for determining who is required to foot the bill for mandatory chemical testing under TSCA Section 4, it is important to consider the new chemical testing paradigm in which the issue of who should pay for chemical testing is being considered. Perhaps the largest single factor contributing to the evolution of the standard against which this decision is being made is the maturation of the “right-to-know” movement, which began when the Emergency Planning and Community Right-to-Know Act (EPCRA) was enacted in 1986. Among other requirements, EPCRA compels the reporting of releases to the environment of listed chemicals from designated facilities. It has changed radically the dynamic between industrial facility operators and the stakeholders to which they are beholden. EPCRA spawned dozens of state and local EPCRA-like laws and the public’s “right-to-know” quickly became the new mantra of the environmental activist community.

Building upon EPCRA’s successes and taking “right-to-know” to its next evolutionary step, the Clinton Administration pushed the envelope further in 1998 in announcing its Chemical Right-to-Know Initiative (CHEMRTK). The CHEMRTK initiative consists of three EPA programs intended to accelerate the collection and dissemination of health data on the most commonly used industrial chemicals. The initiatives include: a challenge to the chemical industry to come forward with “complete data” for the 2,800 chemicals used most widely in the United States; a new testing initiative focused on chemicals children are most likely to encounter; and close

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scrutiny of “persistent” chemicals that accumulate in human tissue.

HPV Challenge Program

The High Production Volume (HPV) Challenge Program was unveiled in 1998 as a cooperative program among the American Chemistry Council (formerly the Chemical Manufacturers Association), Environmental Defense (formerly Environmental Defense Fund, Inc.), and EPA. Testing targets approximately 2,800 chemicals. This listing is based on the TSCA 1990 Inventory Update Rule (IUR). Testing began in 1999, and is expected to be completed by the end of 2004, with various provisions to ensure progress. The chemical industry is projected to spend approximately $500 million on voluntary HPV testing.2

Children’s Chemical Testing

The Voluntary Children’s Chemical Evaluation Program (VCCEP) is an initiative resulting from President Clinton’s Executive Order 13045 issued in April 1997 entitled Protection of Children From Environmental Health Risks and Safety Risks.3 The 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 Order, EPA Administrator Browner established the Office of Children’s Health Protection in May 1997 to facilitate EPA’s effort to protect children from environmental health risks. In April 1998, Vice President Gore announced a new testing initiative focusing on chemicals to which children are most likely to be exposed. EPA then announced its intent to promulgate a children’s health test rule under TSCA Section 4 to obtain health effects data on approximately 50 chemicals believed to adversely affect children and infants disproportionately.4

More recently, EPA and other stakeholders decided to participate in a voluntary initiative—the VCCEP—pursuant to which participants would engage in voluntary testing after an agreed upon list of chemicals, test batteries, and procedures were identified. On April 13, 2000, EPA released its “straw proposal” for a framework for its VCCEP. Under the framework, EPA would request that chemical manufacturers volunteer to sponsor certain chemicals they produce or import and develop or make existing data available in the manner described in the framework.4

EPA states that it will begin this year the VCCEP commitment period, during which companies will be given an opportunity to commit voluntarily to sponsor chemicals. The voluntary commitment period is proposed to run for three months. EPA notes that commitments to the VCCEP are not enforceable agreements or contracts, and sponsor companies may withdraw their sponsorship of a chemical at any time. EPA notes, however, that once a chemical is not sponsored under the VCCEP, it can be considered for inclusion in a forthcoming TSCA Section 4 “children’s health test rule.”

EPA states that the “initial selection of chemicals should be driven by data that demonstrate a high potential for children’s exposure,” including data indicating the presence of substances in: human tissues; food children eat and drink; children’s products; air (especially indoor air); and soil and dust. EPA notes that it considered chemicals that were HPV chemicals and non-HPV chemicals. EPA’s initial selection of chemicals for VCCEP was based on whether monitoring data demonstrated that they are contained in human tissues, including blood, as reported in at least one of the following databases: National Health and Nutrition Examination Survey III (NHANES); National Human Adipose Tissue Survey (NHATS); National Human Exposure Assessment Survey (NHEXAS); and Total Exposure Assessment Methodology (TEAM); and whether the substance is believed to be present in foods children eat and drink or in the air children breathe, based on monitoring data found in at least one of several data sources.5

PBT Strategy

The PBT Strategy is a result of EPA’s persistent, bioaccumulative, and toxic pollutant (PBT) Plenary Group and EPA’s Office Directors’ Multimedian Pollution Prevention (M2P2) Forum.6 The purpose and goal of the PBT Strategy is to reduce further risks to human health and the environment from existing and future exposure to priority persistent,
bioaccumulative, and toxic (PBT) pollutants. The PBT Strategy reinforces, and according to EPA, builds on existing EPA commitments relating to PBTs. Existing initiatives include a 1997 Canada-U.S. Bi-National Toxic Strategy, the North American Agreement on Environmental Cooperation, and EPA’s Clean Water Action Plan.

Endocrine Testing Program

In addition to the CHEMRTK initiative, there are other significant programs intended to identify more precisely the health and environmental risk, if any, of certain chemicals believed to pose higher risk than others. Key among them is EPA’s Endocrine Disruptors Screening and Testing Program (EDSP). In 1996, Congress passed amendments to the pesticide law and amendments to the Safe Drinking Water Act requiring EPA to develop and implement an estrogen screening program. A federal advisory committee, the Endocrine Disruption Screening and Testing Advisory Committee (EDSTAC) developed a report released in 1998, that recommends an extensive battery of screening and testing systems to help predict whether chemicals may act as endocrine disruptors. Early last year, EPA released its “strawman proposal” entitled Draft Priority Setting Process, in which EPA sets forth 12 exposure-related compartments and seven effect-related compartments for the priority setting phase of the EDSP. A total of 80,000 industrial chemicals are being considered for the program, including approximately 2,000 HPV chemicals. These are the testing initiatives receiving the most attention. Others too numerous to summarize here also should not be overlooked.

Concurrent TSCA Section 4 Rulemakings

The Clinton Administration’s emphasis on chemical right-to-know, coupled with its emphasis on knowing more about the health risks posed to susceptible subpopulations, most notably infants and children, has encouraged EPA to use its considerable resources to identify new and innovative ways of jump starting voluntary testing initiatives. The HPV Challenge Program and the VCCEP are the most public examples of them.

Not all testing initiatives are voluntary, however. EPA has, concurrent with the development of these voluntary initiatives, also exercised its more traditional TSCA Section 4 testing authority to compel the production of chemical testing believed essential to address other regulatory needs. Three initiatives are relevant.

Reproductive/Developmental Multisubstance Endpoint Rule—In 1991, EPA proposed developmental and/or reproductive toxicity testing for 10 chemicals. The proposal, which has yet to be issued in final form, is one of several TSCA Section 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 development toxicity of the designated chemicals.

HAP Test Rule—In 1996, EPA issued a TSCA Section 4 test rule in which EPA proposed TSCA Section 4 testing for 21 Hazardous Air Pollutants (HAPs) to help EPA conduct residual risk assessments under the Clean Air Act. Compounds were selected primarily based on their release to air as reported under EPCRA Section 313. All chemicals selected for inclusion in the test rule had reported air emissions in excess of 50 tons in 1993.

Dermal Testing Rule—In 1999, EPA proposed in vitro dermal absorption testing for 47 HPV industrial chemicals pursuant to its TSCA Section 4 authority. The proposal would require entities that manufacture, import, or process any test substances to conduct a dermal absorption test on their chemical products. Data generated would be used by the Occupational Safety and Health Administration (OSHA) for a quantifiable measure of whether skin exposure poses a worker hazard.

These proposals evidence a sustained commitment by EPA to exercise its TSCA authority while at the same time experimenting with non-traditional voluntary initiatives. More importantly, however, a careful read of the who is required to test provisions in each proposal is essential to understand the potentially enormous implications of the test rules that
ultimately may result from the HPV Challenge Program and the VCCEP, and that are driving the parameters pursuant to which entities are volunteering. As discussed more fully below, EPA has sought to impose testing obligations on those entities whose acts have resulted in or contributed to exposures to test chemicals that EPA believes pose health risks. EPA has accomplished this by not exempting from TSCA Section 4 testing obligations classes of entities it has excluded in the past, and by pushing out the jurisdictional reach of TSCA Section 4, an option EPA may have because of the lack of clear definition of the term “manufacture” in TSCA Section 4 and EPA regulations implementing Section 4.

TSCA Section 4 Overview

The mainstay of EPA’s authority to compel health and environmental effects testing is TSCA Section 4. EPA has promulgated detailed regulations governing the development of Section 4 test rules. Under TSCA, each test rule must identify the chemical for which testing is required; contain standards for developing test data; and specify a time period (which cannot be unreasonably long) within which persons required to conduct testing must submit the test data to EPA. In the more than 20 years since TSCA’s enactment, EPA has promulgated test rules addressing approximately 120 chemicals.

While the process itself is relatively uncomplicated, the breadth of EPA’s authority to compel certain classes of entities to pay for TSCA Section 4 testing is plainly evolving and, hence, unpredictable. Although the statute has not changed in any material way for Section 4 purposes since its enactment in 1976, EPA’s jurisdictional reaches over who should pay for TSCA testing has changed, and may well continue to evolve in the years ahead.

TSCA Section 4(b)(3)(B) provides that the following persons “shall” be subject to a test rule:

- “Each person who manufacturers or intends to manufacture” a substance or mixture for which EPA makes a finding that there are insufficient data under Section 4(a)(1)(A)(ii) or Section 4(a)(1)(B)(ii) “with respect to the manufacture of such substance or mixture.”

- “Each person who processes or intends to process” a substance or mixture for which EPA makes a finding that there are insufficient data under Section 4(a)(1)(A)(ii) or Section 4(a)(1)(B)(ii) “with respect to the processing of such substance or mixture.”

- “Each person who manufactures or processes or intends to manufacture or process” a substance or mixture for which EPA makes a finding that there are insufficient data under Section 4(a)(1)(A)(ii) or Section 4(a)(1)(B)(ii) “with respect to distribution in commerce, use, or disposal of such substance or mixture.”

Under the express terms of the statute, therefore, only persons who “manufacture” and/or “process” may be subject to TSCA Section 4 test rules. Additionally, a particular test rule may be applicable to manufacturers only, processors only, or both manufacturers and processors, depending on the findings that EPA makes pursuant to Section 4(a)(1)(A)(ii) and/or 4(a)(1)(B)(ii).

Manufacturers are subject to test rules when the tests are intended to evaluate risks associated with manufacturing, manufacturing and processing, or distribution, use, or disposal. Although processors may be subject to test rule requirements with regard to evaluating risks associated with the same three categories of activities, they seldom are. Historically, processors have been subject to testing requirements only if those requirements are intended to evaluate risks associated solely with processing.

The term “manufacture” is defined by TSCA Section 3 to mean:

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.
regulations define the term “manufacture” for other purposes, however. For example, for purposes of TSCA Section 8(a) general reporting and recordkeeping provisions, EPA defines “manufacture” as “to manufacture for commercial purposes,” and defines “to manufacture for commercial purposes as”:

(1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes among other things, such manufacture of any amount of a chemical substance or mixture:

(i) For commercial distribution, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for commercial purpose.19

Thus, under EPA regulations, a person will be deemed to “manufacture” a test rule substance—and hence be subject to Section 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.” Thus, 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.

Although EPA has not promulgated a definition of “manufacture” specifically for Section 4 test rule purposes, EPA has long asserted authority to regulate byproducts and intermediates when promulgating Section 4 test rules, without any apparent successful challenge. EPA preamble statements imply that EPA also asserts authority to require producers of an impurity to comply with test rule requirements, but historically has chosen not to exercise that authority, although this is not clear.22

It is in these murky waters that EPA is charting new courses. And it is because of the very lack of clarity regarding the precise definition of “manufacturer” for TSCA Section 4 purposes that chemical producers and users of chemicals must take note and assess how these issues may impact their operations. Because of the breadth of EPA’s authority, and the somewhat peculiar interpretation EPA has established with respect to certain key TSCA terms, new classes of chemical “manufacturers” have been identified in recent TSCA proposals, often to the surprise and dismay of the commercial interests newly included in those classes. Examples of these new integrations are noted below.

HAPs Test Rule

The original proposed HAPs test rule broke new and expanded ground in its treatment of byproducts, impurities, and intermediates. EPA treated manufacturers of these HAPs quite differently than prior Section 4 test rules.23 Because it generated so much controversy, it was reproposed and later clarified to address these issues.

The class of persons required to test under the reproposed HAP test rule, as clarified by EPA,24 includes “any person who has, during the last complete corporate fiscal year prior to the publication of the final rule in the Federal Register, manufactured (which includes imported) the HAP chemical at any facility in an amount equal to or in excess of 25,000 lb (regardless of the form of the HAP chemical, i.e., as a Class 1 substance,25 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).”26 In determining the production poundage, the presence
of the test rule substance in a mixture at a concentration of less than one percent is not taken into account. 27

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, in a concentration of less than one percent, would be conditionally subject to the test rule. 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 has submitted a notice of intent to conduct testing. 28 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 non-isolated intermediate would be exempted from the test rule, and, accordingly, from the test cost reimbursement provisions. 29

Dermal Test Rule

The 1999 proposed dermal test rule signaled another important change in EPA’s policy regarding the type of persons subject to future test. The proposed dermal absorption rate test rule sets up a two-tiered approach for persons subject to the rule, and subjects 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 Section 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.” 30

Tier 2 includes persons that: (1) manufacture or intend to manufacture a test rule substance solely as a byproduct, 31 an impurity, 32 a naturally-occurring substance, 33 a non-isolated intermediate, 34 a component of a Class 2 substance as described by 40 C.F.R. § 720.45(a)(1)(i), 35 in amounts of less than 500 kg (1,100 pounds) annually as described in 40 C.F.R. § 790.42(a)(4), 36 and/or in small quantities solely for research and development; 37 and (2) process or intend to process a test rule substance. 38

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 [its] 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 unreasonable burden).” 39 A Tier 1 person who believes that the required testing may be performed by another person, or a consortium of persons, may apply for an exemption from the required testing. 40 All Tier 2 persons, and Tier 1 persons granted exemptions, are subject to EPA’s test cost reimbursement provisions. 41

EPA’s apparent retreat from the broad scope of the persons required to test provisions in the dermal test proposal does not necessarily suggest EPA is reconsidering the position it took in the reproposed and clarified HAP rule. The dermal test data EPA seeks are intended to assist OSHA in identifying worker exposure hazards. Given the focused use of the data and the universe of persons potentially exposed to the test substances, it stands to reason that EPA would define narrowly the persons required to test provisions in that proposal. As workplace hazards constitute a discrete exposure opportunity, EPA quite understandably may have been reluctant to impose testing obligations on producers of the test substance solely as a by-product, as an impurity, naturally-occurring substance, or as a non-isolated intermediate.

The reproposed HAP rule would broadly expand the definition of manufacture for test rule purposes, but impose a volume threshold to limit the universe of persons required to test. EPA reasoned that the broad universe of by-product, impurity, naturally-occurring, and other producers should be required to test, but only if they manufacture over 25,000 pounds per year of the test substance. While narrowing the number of likely entities on the TSCA testing hook with a volume limitation, the scope of the proposal in

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terms of the broadened definition of manufacturer is unprecedented.

Section 4’s Relevance
To Voluntary Testing Initiatives

TSCA Section 4 and EPA’s jurisdictional reach under it to compel chemical testing is highly relevant to voluntary testing initiatives because EPA has made it clear that it will issue a test rule if there are no volunteers to test particular substances. Thus, the likely parameters of a proposed test rule are significant in the decision-making process of entities who are considering whether to volunteer. More specifically, if EPA is unable to attract meaningful participation in voluntary initiatives like the HPV Challenge Program and the VCCEP, EPA has stated its intent to issue TSCA Section 4 rules to obtain health effects data EPA believes are needed to assess risks posed by the test substances. EPA’s interpretation of the scope of TSCA Section 4 in the context of the HAP proposed, reproposed HAP, and dermal test rule may well portend how large a lasso EPA casts over the class of persons required to test for purposes of the HPV and VCCEP rules. As both test rules would compel chemical testing on compounds believed to pose health risks from both ambient and consumer exposures to chemicals, EPA can reasonably be expected to throw a large net over diverse and atypical classes of commercial entities whose activities arguably cause them to be defined as a “manufacturer” for TSCA Section 4 purposes.

TSCA’s Cost Reimbursement Provisions:
A Study in Inadequacy

Of great concern to TSCA Section 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 is using to encourage volunteers, test rule 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 Section 4 test rules and who seek assistance in determining the amount or method of reimbursement. EPA states in the proposed dermal test rule that all Tier 2 persons, and Tier 1 persons granted exemptions, are subject to EPA’s test cost reimbursement provisions. 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. The hearing officer may base his or her proposed order on EPA’s production volume formula set forth in the regulations.

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.” Under EPA’s regulations, production volume includes amounts imported in bulk form, used in mixtures, and produced as a byproduct. 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 Section 12. In the proposed dermal test rule, EPA included in production volume those amounts manufactured as impurities, subject to the discretion of the hearing officer.

Although production volume is identified as the principal criterion on which to base such costs, EPA stated that there “may be situations in which production volume will not give a fair result and other factors or criteria should be used. The relative amount of exposure attributable to each party may be a legitimate factor when different processes or end uses are used by different firms.” Accordingly, even if manufacturers of chemicals ultimately decide to participate in the VCCEP, or other voluntary program, they could argue that their reimbursement obligations should be reduced based on information on reduced exposure arising from production, or other relevant exposure scenarios.
It is important to note that TSCA’s data reimbursement provisions have been employed rarely, if at all. In the proposed dermal test rule, EPA notes that generally, persons subject to TSCA Section 4 test rules “have independently worked out among themselves their respective financial contributions to those persons who have actually conducted the testing.” 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.”

Although companies have seldom, if ever, invoked TSCA’s reimbursement procedures, companies and consortia can, without involving EPA, look to this model as a means to allocate costs. In addition, other organizations have provided guidance as to how testing costs can be allocated between parties. Most recently, the International Council of Chemical Associations (ICCA) launched its Global Initiative to seek sponsors to make available data on 1,000 HPV chemicals by 2004. ICCA recognizes that companies that manufacture such chemicals may seek to form consortia to share testing responsibilities and associated costs, and that a potential stumbling block to forming such consortia is agreeing on how companies will share costs. To assist companies, ICCA provides guidance on how testing costs may be allocated.

It is clear that no standard formula exists under which companies share costs since each consortium has different conditions and priorities. ICCA provides, for example, the following factors that are likely to affect how a cost-sharing arrangement is determined: (1) availability of data (i.e., do the majority of data already exist or do they need to be developed by new testing); (2) characteristics of companies within the consortium (i.e., are there a small number of large firms, a large number of small firms, or some other mix); (3) market characteristics (i.e., are competitiveness or confidentiality major considerations); and (4) company relationships (i.e., do members of the consortium have previous cost-sharing experiences).

ICCA also provides several cost sharing options for companies to consider. These options include allocating costs:

- Based on each company’s share of production globally, domestically, or by some other defined region;
- Based on each company’s nameplate capacity, globally, domestically, or by some other defined region;
- By specific percentages (i.e., equally, negotiated specific percentages, set amounts for small/medium manufacturers plus fixed percentages for large manufacturers); or
- Other legally acceptable methods for cost-sharing based on consensus among members of the consortium.

All of this sounds very rational and orderly. In practice, it has been anything but. Not all companies have well developed senses of product stewardship and, like any other voluntary initiative, some chemical manufacturers will step up to the plate, while others prefer to remain in the weeds. The HPV Challenge Program, the ICCA Initiative, the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) Program, and the VCCEP are all voluntary programs and not all manufacturers of targeted chemicals are volunteering to undertake required testing. Those who do step up are rewarded by whatever minimal public recognition they may receive for doing the right thing. Those who do not step up are not sanctioned in any meaningful or public way. Indeed, their lack of stewardship is effectively rewarded by the "free rider effect." In other words, whatever favorable result that is obtained from the efforts of the volunteers flows equally to the dead beats, whether it is the absence of a TSCA Section 4 test rule or a determination that the chemical poses essentially no exposure risk.

As noted, the cost reimbursement provisions under TSCA are inapplicable to voluntary initiatives. The ICCA has issued guidance on the subject, but it is only meant to guide and is not enforceable. At the end of the day, volunteers are left with little actual recourse and must be content with simply knowing they are doing the right thing. A less satisfying thought is that they are also benefitting their competitors by producing test data that could well serve to keep the chemical on the market with little or no restriction on
the manufacturing or use of the chemical. With respect to older chemicals with narrow profit margins, the added cost of chemical testing could well make the difference between a modestly profitable chemical and an unprofitable one. Unfortunately, EPA's new sense of volunteerism casts a blind eye to these commercial realities.

Fast forward to promulgation of the HPV and children's health test rules. The implications of EPA's evolving Section 4 jurisdictional standard and the fundamental inadequacy of TSCA's cost reimbursement provisions will materialize to an even greater extent. Entities clearly falling into the category of "manufacturer" will have the greatest incentive to comply with a testing mandate. Non-traditional "manufacturers" will likely participate, if at all, however, only reluctantly and after traditional manufacturers have expended considerable resources in explaining how TSCA works and why any such non-traditional manufacturer is also among the chosen "persons required to pay."

Assuming a fair number of entities will continue to question or flat out ignore their testing obligations, others on the TSCA testing hook will face the Hobson's choice of going forward without the support of the recalcitrants or going where no testing consortia has gone before and employing TSCA's cost reimbursement provisions. Neither choice is appealing. As anyone who has participated in a Federal Insecticide, Fungicide, and Rodenticide (FIFRA) data compensation proceeding can attest, AAA arbitrations are every bit as costly and contentious as federal litigation, and the cost of the proceeding could well eclipse the compensation ultimately awarded in the arbitration bringing new meaning to the term Pyrrhic victory. With every challenge comes opportunity, and perhaps the bitter lessons learned from Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) cost allocation battles, coupled with the inherent appeal and renewed vigor of alternative dispute resolution approaches will help promote creative and efficient mechanisms to address these and other quandaries that will soon darken the doorways of many unsuspecting players in the chemical arena.

Conclusion

Persons with business interests in chemicals or in products that contain chemical components that could be alleged to pose chemical release or chemical exposure opportunities are advised to understand well the implications of EPA's new thinking with respect to its authority under TSCA Section 4. As EPA is expected to exercise its broad TSCA Section 4 authority more aggressively to obtain health effects and other test data it believes it needs to make risk assessment judgments, a new and diverse universe of business interests will be invited to participate in paying for the cost of the testing. Indeed, the divisive disputes that arose in the 1980s over cost allocation issues arising under CERCLA could well be repeated in the years ahead. Business interests are urged to take appropriate steps now to understand which of their products, especially consumer products, could provide the basis for EPA's assertion of TSCA jurisdiction, particularly in the VCCEP area, and assess how best to respond to EPA's interest in seeking voluntary commitments to produce necessary test data. The alternative is to roll the dice in defending your business interests in a TSCA Section 4 test rulemaking.

Notes

1 42 U.S.C. §§ 11011 et seq.
2 Chemical Week, June 28, 2000, p. 49 (Testing Programs Take Shape at EPA).
4 The Straw Proposal can be found on the Internet at http://www.epa.gov/opptintr/chemrlk/kdsfr410.htm.
These include: FDA database of Everything Added to Food in the United States (EAFUS); National Contaminant Occurrence Database (includes unregulated drinking water contaminants); NHEXAS; TEAM; and EPA Office of Research and Development studies and other published indoor air data. Using these criteria, EPA developed a draft working list of 45 substances to be considered for inclusion in the VCCEP. These substances include:

Dichlorvos, Acetone, Benzene, Tribromomethane, Vinylidenechloride, Isophorone, Methyl ethyl ketone, Trichloroethylene, 1,1,2,2-Tetrachloroethane, Alpha-pinene, Diethylphthalate, Dibutyl phthalate, Butyl benzyl phthalate, o-Phenylphenol, Naphthalene, Quinoline, o-Xylene, o-Dichlorobenzene, 1,2,4-Trimethylbenzene, Isopropylbenzene, Ethylbenzene, Styrene, Diethyl hexyl adipate, p-Xylene, p-Dichlorobenzene, Ethylene dibromide, Ethylene dichloridem-Xylene, Toluene, Chlorobenzenen-Dodecane, Di-(2-ethylhexyl)phthalate, Di-n-octyl phthalate, Dioxan, Decane, Tetrachloroethylene, 2,6-Di-tert-butyl-p-cresol, m-Diethylbenzene, Hexylacetate, Undecane, Mixed xylenes, (R)-(+)p-mentha-1,8-diene, 1,1,2-Tetrachloroethane, Octamethyclocotetrasiloxane

The Plenary Group consists of programs and technical experts from seven EPA program offices, the Great Lakes National Program Office, and EPA Regional Offices. The Plenary Group’s mission is to develop the PBT Strategy, and identify and resolve issues associated with PBT Strategy implementation.


40 C.F.R. § 790.42(a)(2). Similarly, “persons who manufacture less than 500 kg (1,100 lb) of the chemical annually,” and “persons who manufacture small quantities of the chemical solely for research and development” are subject to a test rule only in certain limited circumstances. Id. §§ 790.42(a)(4)-(5).

The term process is defined as:

(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(B) as part of an article containing the chemical substance or mixture.


See also 40 C.F.R. § 790.42(a) (“Each test rule ... will specify whether manufacturers, processors, or both are subject to the requirement for testing of the subject chemical ...”).

40 C.F.R. § 790.42(a)(1).