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TSCA

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Old TSCA, New TSCA, and Chemical Testing

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The Frank R. Lautenberg Chemical Safety for the 21st Century Act significantly amends the Toxic Substances Control Act (TSCA), including Section 4 concerning the development of information and testing. The Act was signed into law by President Obama and entered into force on June 22, 2016. Amended TSCA has been identified as Pub. L. No. 114-182 (henceforth this article uses ''new'' TSCA to refer to Pub. L. No. 114-182 and ''old TSCA'' when referring to its predecessor (Pub. L. No. 94-469)).

Introduction

I worked in the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) and its predecessor offices for some 32 years. Since the 1980s until my retirement in 2009, I held various technical and management positions that provided longstanding experience in and perspective on using old TSCA's Section 4 to require the development of test data. It is my view that the central failing of old TSCA was its inability to produce the testing needed by EPA to assess and understand the hazards, exposures, and risks of existing chemicals. New TSCA makes important changes to the authority available to EPA to compel industry to generate the information needed by EPA to meet the purposes articulated under the new law.

This paper briefly reviews the issues and problems that EPA encountered in using old TSCA for this purpose, discusses the improvements in new TSCA, and discusses why I believe they offer the potential of future success in the testing area.

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Background on Old TSCA

The basic structure of old TSCA Section 4 required EPA to use rulemaking that involved satisfying legal findings to require testing as summarized below (an *italicized shorthand descriptor* is provided for each finding and **bolding** indicates how the findings operated):

- That certain commercial activities associated with the chemical *may present* an unreasonable risk to human health or the environment; **or**
- That the chemical has substantial production and substantial or significant exposure (*exposure-based*); **and**
- That there are *insufficient data* and experience available to determine the health or environmental effects of the chemical; **and**
- That *testing is neccessary* to develop such data.

A test rule required EPA to develop and issue a proposed regulation and then, after considering comments, promulgate the rule. The rule was required to include the identity of the chemical to be tested, the enforceable ''standards'' by which the testing would be conducted, and the schedule for completing the testing. EPA often made both manufacturers and processors of the chemical subject to the test rule but, in practice, manufacturers fulfilled the requirements without involving processors in conducting the testing. Old TSCA also included

exemption provisions whereby companies otherwise subject to a test rule could request and be granted an exemption from having to conduct the testing, although reimbursement requirements could still apply.

EPA had broad discretion to require needed testing. EPA also developed and codified test guidelines that could be adapted, as needed, in the test rule to obtain enforceable testing on health and environmental effects, environmental fate, and physical-chemical properties (available at 40 C.F.R. Parts 796 through 798). This process involved EPA specifying enforceable ''shall'' requirements in the rule text for the laboratory to apply in conducting the test.

There is litigation history for Section 4 dating back to the 1980s that illustrates the issues EPA faced in requiring testing, including with respect to:

- The *may present* finding, where courts have upheld EPA's test rules where the basis for EPA's ''may present'' finding is ''substantial'' such that ''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.' '' (*Chem. Mfrs. Ass'n v. EPA*, 859 F.2d 977, 988-89 (D.C. Cir. 1988); *See also Ausimont U.S.A., Inc. v. EPA*, 838 F.2d 93, 97 (3d Cir. 1988) (a test rule cannot be ''based on little more than scientific curiosity,'' but the agency can act ''when an existing possibility of harm raises reasonable and legitimate cause for concern'')).
- The *exposure-based* finding, where the court generally upheld EPA's factual findings in the rule, but instructed EPA to ''articulate the standards or criteria on the basis of which it found the quantities . . . to be 'substantial.' ''(*Chem. Mfrs. Ass'n v. EPA*, 899 F.2d 344, 360 (5th Cir. 1990)) In response, EPA promulgated a statement in 1993 interpreting the relevant provision, known as the ''B Policy'' (TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure, 58 Fed. Reg. 28736 (May 14, 1993)) and has since relied upon it.

EPA used its testing authority to require testing on several hundred chemicals over the years, a result that was criticized as inadequate to meet the need. For more information on the issues identified, *See, e.g* U.S. Government Accountability Office, ''Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program,'', GAO-05-458 (June 13, 2005) (GAO Report), available at http://www.gao.gov/products/GAO-05-458. EPA also attempted to use voluntary approaches to obtain testing, with the best example being the High Production Volume (HPV) Challenge program. A link to a description of the HPV Challenge program could not be located on EPA's website; however, archived information is available at https://web.archive.org/web/20150307183557/ and http://www.epa.gov/chemrtk/. Under this program, industry voluntarily agreed to generate and make publicly available basic information on 2,800 HPV chemicals. EPA used the screening information dataset developed by the Organization for Economic Cooperation and Development as the information menu under the HPV challenge. Additional information on the contents and use of the Screening Information Data Set is available at http://acts.oecd.org/Instruments/ShowInstrumentView.aspx?InstrumentID=56&InstrumentPID=53&Lang=en&;Book=False. The HPV Challenge program, although it resulted in public access to significant additional amounts of test data, nonetheless fell short of its goal as shown by GAO's statement that ''the chemical industry has not agreed to provide testing for 300 chemicals originally identified in the HPV Challenge Program'' (*See* GAO Report at 4-5).

I believe that the net result of EPA's efforts to obtain testing information was inadequate to meet EPA's need for information to assess chemicals under TSCA. This failing contributed significantly to the problems that EPA had historically in reviewing and managing the risks of TSCA existing chemicals.

The Promise of New TSCA

The improvements under new TSCA Section 4 begin with its use of the concept of ''information'' as opposed to old TSCA's arguably narrower term ''data.'' Recognizing the weaknesses in old TSCA's rule and findings-based approach to require testing, new TSCA provides additional authority that holds the promise of more effectively enabling EPA to compel industry to generate needed information. EPA also gained explicit authority to require testing for exposure. Finally, in an important development, new TSCA recognizes and brings considerations regarding reducing vertebrate animal (*e.g.*, fish or rodent) testing into the TSCA testing arena.

While old TSCA's rule and findings-based approach is retained (Section 4(a)(1)), new Section 4(a)(2)(A) provides important additional authority, as follows:

- The chapeau gives EPA authority to use rules, orders, and consent agreements under this subsection; and
- In using this authority, per Section 4(a)(2)(A), EPA is not required to make legal findings, but must determine that the testing is necessary for any of several purposes, including to:
  - » Review a notice under Section 5 or perform a Section 6(b) risk evaluation;
  - » Implement a requirement imposed on a new or existing chemical; or
  - » Meet a regulatory testing need requested by another federal agency.

In a very significant enhancement, EPA now has explicit authority (Section 4(a)(2)(B)) to require development of information needed to establish the priority of a chemical under Section 6. Given the well-known limitations on the public availability of test data on chemicals, a fact pattern that led to the development and implementation of the voluntary HPV Challenge, this new authority will be crucially important to the successful realization of an effective prioritization effort. As structured, subsection (i) also requires that EPA make a prioritization decision under Section 6(b) within 90 days of receiving such testing and, upon designating a chemical as high-priority, EPA is required to initiate a

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risk evaluation (Section 6(b)(3)(A)). I read Section 4(a)(2)(B) as intending that EPA use the prioritization testing authority in a somewhat ''metered'' fashion, such that the Agency requires the development of such information when needed to inform prioritization judgments and tee up risk evaluations generally consistent with EPA's available capabilities and resources. Other ''nonmetered'' interpretations may be available, however, although subsection (ii) states that the provision cannot be used to ''establis[h] or implemen[t] a minimum information requirement of broader applicability.''

In using the new authority, EPA is required per Section 4(a)(3) to identify or explain several aspects, including to: identify the need for the new information; describe how reasonably available information was used to inform decisions regarding needed testing; explain decisions to require vertebrate animal testing; and, if using order authority, explain why this approach (*e.g.*, as opposed to rulemaking) is warranted. Finally, Section 4(a)(4) requires that EPA ''employ a tiered screening and testing process,'' whereby the results from the first tier inform decisions regarding higher-tier testing. EPA, however, can proceed directly to advanced testing if it justifies the need.

The new law also makes explicit that EPA can require testing regarding exposure and exposure potential, an aspect that was only implicit in old TSCA. The inclusion of such authority, while exceedingly valuable in EPA's efforts to implement the new law, raises the question of the test methods to be used in conducting exposure studies. While old TSCA used the term ''test standards'' to describe such methods, new TSCA uses ''protocols and methodologies''; both laws require that legally enforceable testing be conducted. This can be seen in the definition of the term at new TSCA Section 3(15): ''The term 'protocols and methodologies for the development of information' means *a prescription* of . . . (i) the manner in which such information are to be developed, (ii) the specification of any test protocol or methodology to be employed in the development of such information, and (iii) such other requirements as are necessary to provide such assurance'' (emphasis added). EPA responded to the requirement for legally enforceable testing under old TSCA in part by undertaking a major multi-year effort to develop an extensive catalog of codified test guidelines, available at 40 C.F.R. Parts 796 through 798, as noted earlier.

While many exposure test methods are available in the literature or from voluntary consensus standards-setting organizations such as ASTM International (https://www.astm.org), EPA will need to adapt those methods to make them enforceable, a process that involves specifying ''shall'' requirements in the rule or order. It is also worth noting that the National Technology Transfer and Advancement Act (Pub. L. No. 104-113) generally directs EPA to use voluntary consensus standards in its regulations, when relevant standards exist and can meet EPA's needs. To the extent that EPA decides to undertake an effort to codify test guidelines for exposure testing, this would likely represent a major scientific effort over many years. This is because of the wide array of such tests that could be relevant to characterizing, as appropriate, consumer, general population, workplace, and environmental (air, water, soil) exposures to TSCA chemicals. Interestingly, the requirement to apply tiered testing also applies explicitly to exposure testing; thus, EPA will need to develop its thinking and approach for screening versus higher tier exposure testing. EPA's Office of Pesticide Programs has exposure test guidelines that were developed for Federal Insecticide, Fungicide, and Rodenticide Act purposes *See, e.g*, EPA, *Series 875 — Occupational and Residential Exposure Test Guidelines*, available at https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-875-occupational-and-residential-exposure), and these exposure test guidelines could serve as a starting point for work under new TSCA.

The inclusion of Section 4(h) and its provisions concerning the reduction and replacement of vertebrate animal testing acknowledge and speak to the emergence of animal welfare as a societal issue of consequence since TSCA's 1976 enactment. The provisions require that EPA:

- ''[R]educe and replace'' the use of vertebrate animals ''to the extent practicable, scientifically justified, and consistent with the policies'' of TSCA (Section 4(h)(1)). In meeting this obligation, EPA is required to:
- ''[Take] into consideration'' ''reasonably available existing information'' including toxicity information, computational toxicology, and high-throughput screening methods; and
- Encourage and facilitate the use of strategies to reduce and replace such testing, group chemicals into categories where testing strategies could be used to develop information on other members of the category, and others.

A good argument can be made that these information sources and tools encompass predictive approaches such as Structure Activity Relationships (SAR) as an alternative to vertebrate animal testing. SAR was developed historically and relied upon by EPA in assessing new chemicals that were frequently notified under TSCA Section 5 without any accompanying test data. Over the past almost four decades, SAR has shown itself to be a most powerful force in reducing vertebrate animal testing under old TSCA and elsewhere in the world. For a more detailed discussion of EPA's approach to SAR under old TSCA, *see* C. Auer and J. Alter, 2007, ''The Management of Industrial Chemicals in the USA,'' *Risk Assessment of Chemicals: An Introduction*, edited by C.J. van Leeuwen and T.G. Vermeire, 553-74. Dordrecht, The Netherlands. For more detailed information on the use of SAR globally to predict fate-related physicochemical properties and health and environmental toxicity endpoints, and to develop intelligent testing strategies, *see* chapters 9 through 11 in *Risk Assessment of Chemicals: An Introduction*.

New TSCA requires that EPA develop and periodically update a strategic plan to promote alternative test methods. There is also a provision concerning voluntary testing intended for submission to EPA that requires the developer to ''first attempt'' to test using alternative methods identified by EPA.

Conclusions

I opened the article with my statement that the central failing of old TSCA was the inability of Section 4 to

produce the information and understanding needed by EPA to assess and manage the risks of existing chemicals. New TSCA provides increased authority, whereby EPA should be able to efficiently and effectively compel the development of needed information for a variety of purposes. As revised, the law offers great potential as a means to ensure that EPA can generate timely information when needed to assess human and environmental toxicity endpoints, and exposure situations and scenarios. The information will be used for the purposes of reviewing new chemicals and for prioritization and risk evaluation of existing chemicals and, thereby, will inform risk management decisions required under the Act. The new law also demonstrates its sensitivity to the current societal tension between the need for testing as a means to provide information and understanding required to protect human health and the environment versus the competing need to reduce and replace vertebrate animal testing when this can be scientifically justified and practicably achieved. I offer my congratulations to all who contributed to the achievement of these stellar outcomes.

In closing, I encourage EPA to apply its new testing authority wisely and appropriately to meet the purposes under the new law, and reflect particular sensitivity in deploying this authority in the case of new chemicals notified under Section 5(a)(1). It is my view that new chemicals for which EPA has made the ''insufficient'' information (Section 5(a)(3)(B)(i)) or ''exposure''-based (Section 5(a)(3)(B)(ii)(II)) determinations under new TSCA should be allowed to enter commerce while testing requirements are met over time. In my experience while running the Section 5 program at EPA, the usual regulatory outcome for ''exposure-based'' new chemical cases was limited to a Section 5(e) consent agreement imposing ''triggered'' testing requirements. Under this approach, the needed testing was required to be developed following commercialization based on a time or volume ''trigger'' that specified when the test data reports needed to be submitted. I believe, based on my experience while at EPA, that upfront or too-heavy a testing burden can have a stifling effect on commercialization of new chemicals. This would be unfortunate if realized as, over the course of my EPA career, I came to see new chemicals as a source of continuous innovation in the introduction, over time, of progressively safer and greener chemicals. I encourage EPA to apply both the letter and spirit of new TSCA Section 2(b) to ensure that new chemicals continue to be healthy contributor to innovation:

''It is the policy of the United States that — (1) adequate information should be developed with respect to the effect of chemical[s]. . .on health and the environment and that the development of such information should be the responsibility of those who [manufacture and process such chemicals]; . . . (3) authority over chemical[s]. . .should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical[s]. . .do not present an unreasonable risk . . .to health or the environment.''

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