Analysis&Perspective

TOXIC SUBSTANCES

CHEMICALS OF CONCERN

The Toxic Substances Control Act allows EPA to keep a list of chemicals that present or may present ''an unreasonable risk of injury to health or the environment.'' This authority has not been used since TSCA was enacted in 1976. In April, EPA said it intends to propose a rule to add a category of eight phthalates, a category of polybrominated diphenyl ethers, and bisphenol A to such a list. In this article, the authors explore EPA's authority under Section 5(b)(4) of the TSCA to create a ''chemicals of concern'' list and discuss legal and policy issues that may arise.

TSCA Section 5(b)(4) 'Chemicals of Concern' List: Questions, Issues, Concerns

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As part of efforts to enhance the Environmental Protection Agency's chemical management program under the Toxic Substances Control Act,[1] EPA has released a series of ''action plans'' on chemicals.[2] These ''CAPs,'' as they have come to be called, summarize available hazard and exposure information pertinent to the CAP chemical, outline potential risks believed to be presented by the chemical, and identify steps EPA is taking to address the concerns raised.

Through April 2010, EPA has released action plans on five chemicals or chemical groups—phthalates; long chain perfluorinated chemicals; penta-, octa-, and decabromo diphenyl ethers (PBDEs) in products; short-chain chlorinated paraffins; and bisphenol A (BPA).

Three of the action plans (phthalates, PBDEs, and BPA) indicate EPA intends to add the chemicals to a ''chemicals of concern'' list that would be created using EPA's authority under TSCA Section 5(b)(4)(A)(i). EPA noted in its April 26, 2010, Regulatory Agenda that it intends to publish in September 2010 a proposed rule adding a category of eight phthalates, a category of PBDEs, and BPA to a Section 5(b)(4) list.[3]

Although EPA expressed interest in using this authority during President George W. Bush's administration, the provision has never been used over the 34 years of TSCA's existence. This paper explores EPA's authority under TSCA Section 5(b)(4) to create a ''chemicals of concern'' list and discusses legal and policy issues that may arise in its implementation.

Legal Background

TSCA Section 5(b)(4)(A)(i) provides that EPA ''may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, . . . or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.'' TSCA Section 5(b)(4)(A)(ii) requires that in making this finding, the administrator ''shall consider all relevant factors, including. . .'' the chemical's health and envi-

[1] 15 U.S.C. §§ 2601-2629.

[2] EPA, Existing Chemicals Action Plans, http://www.epa.gov/oppt/existingchemicals/pubs/ecactionpln.html; C. Auer, *et al*. Env. Law Rptr. 40: 10243, 2010.

[3] 75 Fed. Reg. 21872 (Apr. 26, 2010).

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ronmental effects and the magnitude of human and environmental exposure. Pursuant to Section 5(b)(4)(B), in developing the rulemaking EPA is also required to ''identify those uses, if any,'' of the substance that would constitute a significant new use as determined under a Section 5(a)(2) rule.

TSCA Section 5(b)(4)(C) imposes additional requirements on the rulemaking procedures, including an opportunity for an oral presentation in addition to written comments, a requirement that a transcript be prepared for any such oral presentation, and a requirement that EPA publish with any rule the basis for its findings as described in TSCA Section 5(b)(4)(A).

The 'May Present' Finding

The finding of ''may present'' an unreasonable risk also appears in TSCA Section 4(a)(1)(A)(i) relating to development of test rules and in Section 5(e)(1)(A)(ii)(I) concerning actions regulating new chemicals or significant new uses of chemicals pending development of information. In Section 4 test rules, EPA has generally relied on the results of data on a test chemical to support the hazard portion of the risk finding and on available information pertinent to exposures, uses, and releases to support the exposure portion of the finding.[4] In implementing Section 5(e) for control of new chemicals pending development of information, EPA generally finds itself with few or no test data on most new chemicals. As a result, EPA has developed and relies on the results of Structure Activity Relationships (SAR) analysis supplemented by any available test data to support the hazard portion of the finding and the information supplied in the notice to support the exposure assessment.[5] Thus, in developing ''may present'' findings under both TSCA Sections 4 and 5, EPA generally has relied on preliminary risk conclusions based on available, often limited hazard data or SAR arguments and basic exposure information to yield a qualitative or semi-quantitative risk finding.

EPA's approach under Section 4 has been the subject of considerable debate and legal challenge. The decisions in these cases have helped clarify the burden of proof required to support a ''may present'' finding under Section 4 and thus may be useful in interpreting EPA's legal burden under Section 5(b)(4).

In *Shell Chemical Co. v. EPA*, decided in 1987, Shell Chemical challenged a final Section 4 test order requiring it and other manufacturers and processors of mesityl oxide (MO) to test the substance. Shell Chemical argued that the Section 4 test rule was not supported by ''substantial evidence,'' as is required under TSCA.[6] The case was remanded to EPA based on the availability of new information. The court provided no new guidance on how strong an evidentiary showing of ''substantial risk'' must be to merit a test rule.

In *Ausimont USA, Inc. v. EPA*, a 1988 decision, manufacturers challenged EPA's final Section 4 test rule for fluoroalkenes, arguing that ''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.''[7] The Third Circuit held that EPA could not require testing ''based on little more than scientific curiosity'' but that testing may be compelled ''when an existing possibility of harm raises reasonable and legitimate cause for concern.''[8] In construing the statutory ''may present'' phrase, the court stated: ''The necessity for testing depends on lack of knowledge. If no doubt existed, testing would not be required and the 'actual' risk concept espoused by petitioners would have little meaning. Likewise, if EPA views 'potential' exposure as merely a remote possibility founded on theoretical factual situations, the statutory directive for 'reasonable and prudent' agency action would counsel against expensive testing.''[9]

In *Chemical Mfrs. Ass'n v. EPA*, also decided in 1988, the Chemical Manufacturers Association (CMA) and four manufacturers of 2-ethylhexanoic acid (EHA) challenged EPA's proposed rule compelling new data. The need for new data was based on certain studies cited by EPA as suggesting that EHA ''may present an unreasonable risk'' of certain adverse health effects and other information indicating a ''potential danger that EHA will come in contact with the skin of workers.''[10] CMA argued that EPA is required to find under Section 4 that the existence of an ''unreasonable risk of injury to health'' is ''more-probable-than-not'' to support a test rule. EPA argued that the standard was ''satisfied where the existence of an 'unreasonable risk of injury to health' is a substantial probability—that is, a probability that is more than merely theoretical, speculative or conjectural.''[11]

The court upheld EPA's interpretation of TSCA and concluded that EPA ''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'' and ''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.' ''[12]

The court further upheld EPA's construction of Section 4 that ''[s]o 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.''[13]

These cases provide some judicial gloss on the standard EPA is held to in supporting Section 4 test rules. It is, of course, unclear at this early date how EPA intends to support any legal findings under Section 5(b)(4). It would appear, however, based on these Section 4 precedents that certain kinds of readily available informa-

[4] Risk assessment involves an integrated assessment of hazard (or toxicity) and exposure data and information.

[5] C Auer and J Alter, ''The Management of Industrial Chemicals in the USA,'' in *Risk Assessment of Chemicals: An Introduction,* 2nd ed., edited by CJ van Leeuwen and TG Vermeire, Springer, pp. 553-574, 2007.

[6] *Shell Chemical Co. v. EPA*, 826 F.2d 295, 297; 26 ERC 1528 (5th Cir. 1987).

[7] *Ausimont USA, Inc. v. EPA*, 838 F.2d 93, 95; 27 ERC 2235 (3rd Cir. 1988).

[8] *Id.* at 97.

[9] *Id.*

[10] *Chemical Mfrs. Ass'n v. EPA*, 859 F.2d 977, 980-81; 28 ERC 1510 (D.C. Cir. 1988).

[11] *Id.* at 983.

[12] *Id.* at 990-991.

[13] *Id.* at 991.

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tion, when integrated to produce a screening level risk assessment, could well suffice to support a finding of ''may present an unreasonable risk'' for these purposes. EPA may claim some or all of the following as sources, among others, that, by themselves or in some combination, may suggest a ''more than theoretical'' basis that a substance ''may present'' an unreasonable risk of injury to health or the environment:

- Screening level hazard data on a chemical from the High Production Volume (HPV) Challenge Program,[14] and SAR analyses using data on analogous chemicals (or both) showing the potential for health or environmental effects;
- ''Exposure/use'' information reported under the Inventory Update Rule;[15]
- Data collected under TSCA Section 8(e) when manufacturers, processors, and distributors of chemical substances or mixtures submit ''information which reasonably supports the conclusion that [a] substance or mixture presents a substantial risk of injury to health or the environment'';[16]
- Information on toxic chemical releases and waste management activities reported by certain industries as well as federal facilities under the Emergency Planning and Community Right-to-Know Act Toxics Release Inventory;[17] and/or
- Human biomonitoring information collected by the Centers for Disease Control and Prevention in its National Report on Human Exposure to Environmental Chemicals.[18]

Importantly, in the case of the three CAP chemicals/groups of chemicals that EPA has identified for Section 5(b)(4) listing consideration, considerably more detailed information is available on both hazards and exposures than is represented by these sources. This would suggest that as to these listings, EPA may meet and exceed the burden required under the Section 4 ''may present'' standard.

Legal Effects of Listing

A chemical that has been added to the Section 5(b)(4) list can be subject to additional TSCA requirements:

- Pursuant to Section 5(b)(2)(B), any required notice to EPA under Section 5(a) concerning such a chemical as a ''new chemical'' or as a ''significant new use''[19] must include data that the notifier believes show that the new chemical or the significant new use ''will not present an unreasonable risk.''
- EPA is allowed to eliminate by rule (Section 8(a)(3)(A)(ii)(II)) the small manufacturer/small processor exemption that otherwise applies to reporting for such chemicals under Section 8(a) information gathering rules; and
- Requirements for export notification under Section 12(b) *may* be triggered.

The legal effect of the first of these is to flip the burden of proof from EPA to the notifier in submitting new chemical or significant new use notifications, whereas the second would allow EPA to obtain exposure, use, and/or other information on the subject chemical from small businesses otherwise exempted from reporting under Section 8(a). The question of triggering the requirement for export notification is a bit more complicated.

Section 12(b)(1) requires export notifications for chemicals ''for which the submission of data is required under [Section 4 or 5(b)].'' Section 12(b)(2) requires export notifications for chemicals ''for which an order has been issued under [Section 5] or a rule has been proposed or promulgated under [Section 5 or Section 6].'' Based on the foregoing, many may claim that export notification requirements under Section 12(b)(1) would attach only if EPA issues a *final* Section 5(b)(4) rule that compels the submission of information on a chemical otherwise also subject to a premanufacture notification (PMN) (Section 5(a)(1)(A)) or significant new use notification (SNUN) (Section 5(a)(1)(B)) data reporting requirement which, because of the Section 5(b)(4) listing action, would need to be accompanied by ''data'' that the notifier believes show that the chemical will not present an unreasonable risk. Notice of the availability of such ''will not present'' data may well be of interest to the government of the importing country. Others suggest that the broad reference to ''Section 5'' in Section 12(b)(2) triggers export notification for any proposed *or* final Section 5(b)(4) rule, regardless of any requirement regarding the submission of data.

Based on EPA's website representations, it appears that EPA espouses the latter interpretation and that Section 12(b)(2) empowers it to impose export notification requirements when it *proposes* a Section 5(b)(4) rule. EPA's website specifically states that ''anyone who exports or intends to export a chemical substance that is the subject of a *proposed* TSCA section 5(b)(4) rule are subject to the export notification provisions.''[20] While TSCA's legislative history is a bit unclear on this point, it provides a reasonable basis to question whether EPA's apparent interpretation of the effect of a proposed Section 5(b)(4) listing is too broad.

The view that no export notification requirements are triggered purely by a proposed or even final listing under Section 5(b)(4) finds support in a close parsing of the legislative history. The provision in TSCA that is now Section 5(b)(4) originated in the House bill as Section 5(c)(2),[21] which required EPA to compile a list of chemicals that, in part, may cause or significantly contribute to an unreasonable risk. If a new chemical substance or a significant new use of a chemical substance was included on the list, the manufacturer (or proces-

[14] http://www.epa.gov/hpv/.
[15] http://www.epa.gov/oppt/iur/.
[16] TSCA § 8(e), 15 U.S.C. § 2607(e).
[17] http://www.epa.gov/tri/.
[18] http://www.cdc.gov/exposurereport/.
[19] Chemicals not listed on the TSCA Inventory that are intended for commercial introduction are considered new chemicals subject to prior notification under Section 5(a)(1)(A), whereas chemicals for which the notifier intends to commercialize for a significant new use, as determined by a Significant New Use Rule under Section 5(a)(2), are subject to prior notification for the significant new use under Section 5(a)(1)(B).
[20] EPA, TSCA Section 5(b)(4) Concern List, available at http://www.epa.gov/oppt/existingchemicals/pubs/sect5b4.html (emphasis added) (last updated Apr. 22, 2010).
[21] Legislative History of the Toxic Substances Control Act together with a Section-by-Section Index prepared by the Environment and Natural Resources Policy Division of the Library of Congress for the House Committee on Interstate and Foreign Commerce (Dec. 1976) at 322-323 (H.R. 14032).

sor) would submit a PMN or SNUN, respectively, to EPA. In these earlier TSCA versions, export notification requirements under Section 12(b)(1) were triggered only for chemical substances for which the submission of data were required under Sections 4 or 5(d).[22] The then Section 5(d) ''Requirement Respecting Submission of Test Data'' is what eventually became Section 5(b)(1)-(3) and did not include Section 5(c)(2) (now Section 5(b)(4)). Thus, a reasonable interpretation of this legislative history supports that view that referring only to TSCA Section 5(b) in the final version of TSCA Section 12(b)(1) was meant to refer to Section 5(b)(1)-(3), and not Section 5(b)(4). If any export notification requirements are to apply, the logical upshot of this is that EPA would lack authority to compel the submission of TSCA Section 12(b) export notifications for any Section 5(b)(4) listed chemical except those final rules that specifically required the submission of data.

Other Effects of Listing

In addition to the legal effect of listing a chemical under Section 5(b)(4), whatever they are ultimately determined to be, such a list, even at the proposed rule stage, could have potentially significant collateral implications that will almost certainly impact the way that listed chemicals are perceived and treated by various entities. It is in these impacts that a Section 5(b)(4) listing may have its most dramatic impact.

The potential for Section 5(b)(4) listed chemicals to be present widely in both commercial and consumer products would seem to present new opportunities for stakeholders, and in particular consumers and chemical product detractors, to raise concerns, particularly given the increasing recognition of and concern with chemicals in household, consumer, and children's products. In addition, while EPA has not previously created a listing of chemicals that ''present or may present'' an unreasonable risk, other EPA listings including the list of Hazardous Air Pollutants under the Clean Air Act, drinking water contaminants under the Safe Drinking Water Act, and chemicals listed on the EPCRA Toxics Release Inventory, among others, have had effects far beyond the basic listing. Among the possible reactions to and uses of a Section 5(b)(4) list include:

- Chemical manufacturers are likely to see it as having a ''black list'' effect on listed chemicals and will be concerned that the risk basis for the listing may be misunderstood or overstated.
- Downstream commercial entities may see it as providing reason for them to investigate alternative substances to formulate safer products and/or restrict the distribution of products containing listed chemicals.
- Environmental groups will likely welcome it as an effort to highlight ''problem chemicals.''
- States may draw chemicals from the list for restriction or ban actions that they take.
- Congress may draw from it in developing lists for possible use in a revised TSCA.

Use of the list to provide understanding and identify *potential* problems may be an appropriate use of the information. Nonetheless, it is likely that the subtle nuances and legal limitations and uncertainties in EPA's ''may present an unreasonable risk'' finding will be lost once the list has been created.

Conclusions

Developing a TSCA Section 5(b)(4) ''Chemicals of Concern'' list is one of the tools EPA is using to discharge more effectively and leverage its TSCA authority. EPA's development of a Section 5(b)(4) list should be monitored carefully so that legal, commercial, and optical issues can be promptly identified and effectively managed. How similar issues have been addressed under other sections of TSCA provides guidance on how issues will be addressed with Section 5(b)(4). Other issues, however, are more novel and, as issues of first impression, require ingenuity and vision in resolving effectively.

[22] *Id.* at 368.

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