

## Washington Watch

### Old Dogs and New Tricks: US EPA Gets Creative with TSCA

*Proposed SNURs and enhanced chemical management*

**Lynn L. Bergeson**

The United States Environmental Protection Agency (US EPA) has taken some bold steps recently to strengthen its authority over existing chemicals — using its expansive, but much maligned, authority under the Toxic Substances Control Act (TSCA). TSCA is an old statute, and believed by many to be out of date. But in “repurposing” its interpretation of its TSCA authority, US EPA has confirmed that the statute is more than a paper tiger.

This column focuses on a key aspect of US EPA’s new TSCA thrust: proposed significant new use rules (SNURs) that would require companies to report all “new uses” for five groups of chemicals. After some background discussion, the column examines these proposed SNURs, in which the Agency seeks to expand its customary reach under TSCA. The proposals give new insight into the age-old question of whether old dogs can learn new tricks.

#### **Background: Enhanced Chemical Management**

Enhanced chemical management has been a central component of the Obama Administration’s environmental platform. On September 29, 2009, US EPA Administrator Lisa Jackson announced the Administration’s core principles for TSCA legislative reform. At the same time, she set out the Agency’s plans to strengthen its current chemical management program and increase the pace of its efforts to address chemicals that are believed to pose a risk to the public.

While the Obama Administration believes that TSCA legislative reform is necessary for an effective chemicals management program, it has offered no proposed legislation on the subject. Nonetheless, Administrator Jackson has repeatedly stated that US EPA is committed to strengthening the performance of the Agency’s current chemical management program as legislative efforts progress.

## ***Chemical Action Plans***

Enhancements initially included the development of chemical “action plans” that outline US EPA’s risk management efforts on those chemicals it believes to be of greatest concern. The plans outline bold steps to control chemical exposures of concern, utilizing an array of voluntary and mandatory measures under TSCA, including section 5 SNURs, chemical testing rules under TSCA section 4, chemical restrictions or bans under TSCA section 6, and voluntary agreements with chemical manufacturers, among other tools.

The Agency’s initial list of chemicals being considered for action plan development contained no major surprises. It included benzidine dyes and pigments, bisphenol A (BPA), polybrominated diphenylethers (PBDEs) in products, long-chain perfluorinated chemicals (PFCs), phthalates, and short-chain chlorinated paraffins (SCCPs).

US EPA stated that it chose these initial chemicals for action plan development on the basis of multiple factors. The Agency focused on chemicals identified as persistent, bioaccumulative, and toxic (PBT); high production volume (HPV) chemicals; chemicals in consumer products; chemicals of particular potential concern for children’s health because of reproductive or developmental toxicity; chemicals subject to review and potential action in international forums; chemicals found in human blood (based on biomonitoring programs); and chemicals in categories generally identified as being of potential concern in US EPA’s New Chemicals Program.

## ***Identifying “Priority Chemicals”***

The Agency expanded on these efforts in August 2011, when it released a strategy for identifying priority chemicals for review. The strategy, which describes a two-step approach for assessing existing chemicals, addresses risk assessment and risk reduction, data collection and screening, and public access to chemical data and information.<sup>1</sup>

## ***Work Plan for Chemical Review***

On March 1, 2012, the Agency added another element to its Enhanced Chemicals Management Program: a work plan for further review of 83 chemicals under TSCA. US EPA identified seven of these chemicals for risk assessment in 2012.<sup>2</sup>

The Agency plans to complete some of the assessments this year and will initiate new assessments from the work plan in following years. During

2012, US EPA plans to identify specific chemicals for risk assessment in 2013 and 2014.

### **Proposed SNURs for Five Chemical Groups**

US EPA has proposed SNURs addressing five chemical groups, each of which was included in the Enhanced Chemicals Management Program that was rolled out in September 2009. The chemical groups are:

- certain PBDEs,<sup>3</sup>
- hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane (collectively referred to as HBCD),<sup>4</sup>
- benzidine dyes,
- di-*n*-pentyl phthalate (DnPP),
- certain SCCPs.<sup>5</sup>

The proposals reflect US EPA's continuing use of existing TSCA authorities to achieve the Administration's commitment to enhanced chemical management.

The discussion that follows focuses in particular on the proposed PBDEs SNUR, which best reflects the precedent-setting nature of the Agency's new approach to enhanced chemical management. Before considering the unique aspects of this proposed rule, however, a brief overview of US EPA's SNUR authority is helpful.

### **US EPA's SNUR Authority: An Overview**

When US EPA promulgates a SNUR, it effectively designates a use of a chemical as "new" and subjects that use to premarket review by the Agency — even though the use may not be "new" as the term is commonly understood. At the least, a use that is covered by a SNUR is one that is not ongoing (or considered a use in commerce) at the time US EPA proposes to treat it as new.

When a use is designated as "new" for a particular chemical substance, then manufacturers, importers, and/or processors of that chemical substance must submit a significant new use notice (SNUN) to US EPA at least 90 days before they engage in any manufacture, import, or processing for that use.<sup>6</sup> For all practical purposes, a SNUN requires the same

information as a TSCA premanufacture notice (PMN).

Upon review of a SNUN, US EPA can exercise the same authority it may take with respect to a newly filed PMN. Specifically, the Agency can obtain health or environmental test data, take action to protect against risks it believes to be unreasonable (including regulating the manufacture, processing, distribution, use, or disposal of the substance), or take action to protect against imminent hazards as provided under TSCA sections 5(e), 5(f), 6, or 7.<sup>7</sup>

If US EPA takes no such action in response to the SNUN, it must publish a notice in the *Federal Register* explaining its reasons for failing to take action.<sup>8</sup> The uncertain outcome of Agency PMN and SNUN reviews is the bane of commercial entities' quest for commercial certainty and predictable outcomes. Reviews can (and often do) take considerably longer than 90 days. Moreover, US EPA's TSCA authority can be expressed through the imposition of any number of new commercial restrictions or operating conditions, some of which may need to be communicated to downstream customers of the PMN/SNUN submitter.

With these basics in mind, we now consider PBDEs and the SNUR amendments that have been proposed for them.

## **Proposed SNUR for PBDEs**

### ***Understanding PBDEs***

According to the Agency for Toxic Substances and Disease Registry (ATSDR), PBDEs are synthetic chemicals that are widely used in many commercial and consumer products. They are considered valuable in large part because of their flame-retardant properties.

PBDEs exist as mixtures of similar chemicals referred to as "cogeners." These chemicals share a common structure of a brominated diphenyl ether (BDE) molecule that may have from four to ten bromine atoms attached to it. Commercial forms of PBDEs include pentaBDE, octaBDE, and decaBDE. Each commercial product is a mixture of PBDE cogeners.

US EPA has expressed concern about reported health and environmental effects of PBDEs and potential exposure to them. ATSDR reports that because PBDEs are mixed into plastic and foams (rather than being bound to them), they can migrate from the products and enter into the environment. US EPA states that "PBDE cogeners with four to ten bromine atoms are highly persistent, based on a large body of

environmental monitoring data in both the United States and abroad.”<sup>9</sup>

### ***Past Regulatory Activity***

Over the years, US EPA has taken several regulatory actions aimed at better understanding the effects of PBDEs and reducing exposure to them. PBDEs were the subject of a SNUR issued on June 13, 2006.<sup>10</sup> That SNUR complemented the phase-out of pentaBDE and octaBDE, two chemicals that domestic manufacturers had voluntarily agreed to phase out of production in November 2003 (with phase-out to be complete by December 31, 2004).

Because US EPA was concerned that the manufacture or import of these PBDEs could be “reinstated” in the future, the Agency issued the SNUR to ensure that it would have an opportunity to assess any new manufacture or import of these chemicals before such activity commenced. Under the existing SNUR, any person who intends to manufacture these (or four other) PBDEs must notify US EPA at least 90 days before commencing the manufacture of any one or more of them for any new use.<sup>11</sup>

PentaBDE, octaBDE, and decaBDE were also among the chemical substances assessed in the Agency’s Voluntary Children’s Chemical Evaluation Program (VCCEP). VCCEP was designed to collect health effects information on chemicals to which children had a high likelihood of being exposed and to characterize the risk to children from that exposure.

US EPA has weighed in on voluntary consensus standards for PBDEs, supporting restrictions on their use in manufacturing processes or as product components (e.g., in carpets, electronics, and furniture). The Agency has also worked with and through programs (e.g., the Furniture Flame Retardancy Partnership and the Green Suppliers Network) to identify environmentally safer approaches to meeting fire standards and to improve awareness of concerns related to PBDEs.

The domestic PBDE industrial chemical community has been very much a part of the discussion regarding PBDEs and their beneficial applications, as well as their potential human health and environmental implications. As noted, the domestic producers of pentaBDE and octaBDE voluntarily agreed to phase out production by December 31, 2004.

On December 19, 2009, the three domestic producers of decaBDE agreed voluntarily to phase out decaBDE production in the United States. Under the terms of the agreement with US EPA, the companies committed to end production, importation, and sales of decaBDE for most uses in the United States by December 31, 2012, and to cease all uses by the end of

2013.

US EPA has proposed several significant amendments to the existing PBDE SNUR issued in 2006. The proposal is noteworthy for three reasons, as discussed in the following paragraphs.

### ***Elimination of the Article Exemption***

Under US EPA rules, persons who import or process a SNUR substance “as part of an article” generally are exempt.<sup>12</sup> In the proposed PBDEs SNUR, however, the Agency would eliminate this exemption.

According to US EPA, “No person would be able to begin manufacturing, importing, or processing, including as contained in an article, any of the chemical substances identified in the proposed SNUR for a significant new use without first submitting a significant new use notification (SNUN).”<sup>13</sup> The Agency makes clear that “ongoing uses” would be excluded from the SNUR because such uses can never be considered “new” under TSCA.

### ***“Processing” Provisions***

Second, the proposed SNUR would designate “processing” (in addition to the more routine manufacturing and importing) as a significant new use. The proposal would apply to decaBDE and to the original six PBDEs regulated under the SNUR for any use that is not ongoing after December 31, 2013.<sup>14</sup>

“Processing” has not previously been considered a significant new use for these PBDEs. Further, US EPA would designate the manufacture (including import) or processing of any article to which these PBDEs have been added as a significant new use.

### ***Section 4 Test Rule***

Third, to further incentivize the cessation of PBDE use, the proposed SNUR contains an onerous TSCA section 4 test rule for pentaBDE, octaBDE, and decaBDE. US EPA intends to promulgate the test rule if it determines that manufacture (including import) or processing of PBDEs, including in articles, has not ceased by December 31, 2013.<sup>15</sup>

The test rule would require development of significant toxicity data, including data on chronic toxicity for pentaBDE and octaBDE.<sup>16</sup> US EPA believes this information is necessary to determine the effects on human

health of manufacturing, processing, or other activities involving these PBDEs. The Agency estimates that the studies required under the test rule will cost over \$2 million for decaPBDE alone.

The Agency has proposed a two-tiered testing scheme that places the testing burden on Tier 1 entities in the first instance. Tier 1 entities include persons who manufacture or import mixtures containing the test-rule PBDEs (including importers of articles). Tier 2 includes processors and persons who manufacture these PBDEs only in small quantities as R&D materials, in amounts less than 500 kilograms, or solely as byproducts, impurities, naturally-occurring chemical substances, and/or in non-isolated intermediates.<sup>17</sup>

The test rule would apply to both ongoing and new uses of the relevant PBDEs. If US EPA determines that the only entities subject to the rule are persons that process the PBDEs solely as impurities in articles, the Agency would not require testing. This is because US EPA has not determined (as required under TSCA section 4) that this activity alone may present an unreasonable risk of injury to health or the environment.

### **Proposed SNUR for HBCD**

The proposed SNUR for HBCD would designate “use in consumer textiles, other than for use in motor vehicles” as a significant new use. Persons who intend to manufacture (including import) or process HBCD for use in covered consumer textiles would be required to notify US EPA at least 90 days before commencing that activity. For purposes of this proposed rule, the Agency states that the general SNUR exemption for persons who import or process chemical substances as part of an article would not apply.<sup>18</sup>

### **Proposed SNUR for Benzidine Dyes, DnPP, and Certain SCCPs**

US EPA has proposed rules that would add nine benzidine-based chemical substances to the existing SNUR on benzidine-based chemical substances.<sup>19</sup> The proposals would also create SNURs for DnPP and for alkanes, C<sub>12-13</sub>, chloro (which are SCCPs).<sup>20</sup>

For the benzidine-based chemical substances, the Agency would eliminate the article exemption (as it also proposes to do in the SNURs on PBDEs and HBCD). Thus, the exemption in 40 CFR section 721.45(f) relating to persons that import or process SNUR substances as part of an article would not apply. This means that persons who intend to import or process any of the nine newly proposed benzidine-based chemical

substances (or any currently listed benzidine-based chemical substance) as part of an article would have to notify US EPA at least 90 days before commencing that activity.

### **Implications of US EPA's SNUR Proposals**

These proposed SNURs represent important steps by US EPA in furtherance of its Enhanced Chemicals Management Program. They also constitute an important body of work that will need close scrutiny by affected entities.

The proposed SNUR on PBDEs breaks new ground by including processing as a significant new use. In addition, the proposed SNURs for PBDEs, HBCD, and certain benzidine-based chemicals set a new precedent by including manufactured articles.

### ***Burden on Commenters***

Importantly, in the proposed PBDEs SNUR, the Agency places a significant burden on commenters to explain "the extent to which these uses will continue . . . and whether there are any other uses which will not be discontinued by December 31, 2013."<sup>21</sup> In discussing this aspect of the proposal, US EPA asks for details on ongoing uses and requests definitions of terms.

This suggests that the Agency may narrowly define any ongoing uses based on the information provided in comments. It will be important for commenters to make sure that information provided to US EPA on any ongoing uses is comprehensive in its coverage and described as precisely as possible. It also begs the issue that has been raised in comments as to whether US EPA's "once size fits all" approach to eliminating the article exemption is the best (or only) way to go. Some have suggested that the Agency should develop a more refined subset of articles, a subset targeting articles that may actually give rise to an exposure risk to human health or the environment, rather than including all articles within the scope of the SNUR.<sup>22</sup>

Other important issues that are not framed in the rulemakings are the threshold question of whether US EPA should expand the scope of its SNUR authority in this way, and the practical implications of doing so. On the one hand, the Agency is to be commended for seeking to use the tools it has to address potential chemical risks. On the other hand, whether TSCA's SNUR authority is the best way to address chemical risks, and whether all articles

as defined in the proposal present risks worth regulating, deserves greater stakeholder discussion.

Comments in response to *Federal Register* notices that assume the legitimacy of US EPA's legal and policy approach are a poor surrogate for vigorous public debate. A key reason for this is that, while chemical manufacturers and importers are well aware of SNURs, SNUNs, and the implications of these terms, their downstream customers and article manufacturers are less familiar with TSCA and may be completely oblivious to the proposed rules and their game-changing commercial implications.

### ***Recycling of PBDEs***

Another interesting aspect of the proposed SNURs is the extent to which recycling of PBDEs will be impacted after 2013. Recycling is considered "processing." Because US EPA has also proposed a test rule for certain PBDEs, the Agency will need to consider carefully any comments about ongoing uses or processing, and the magnitude (volume) of such activities, in preparing the final test rule.

The Agency must avoid discouraging reclamation activities or saddling plastic reclaimers with costly testing burdens or cost-reimbursement obligations. In its proposal, US EPA clarifies that persons who "grind old plastic pallets containing decaBDE for the purpose of reusing the ground material in the fabrication of 'new' plastic pallets would be considered processors of decaBDE as an impurity, if the decaBDE is unintentionally present in the recycled product . . . ." <sup>23</sup>

It is important to keep in mind that a test rule may never be issued in final form. US EPA has made clear in its proposal that a final rule will be issued only if the Agency determines that there are persons who intend to manufacture, import, or process one of the SNUR PBDEs after December 31, 2013. Nonetheless, if US EPA does issue the test rule, recyclers would be considered Tier 2 entities. Recyclers would not be subject to Tier 1 testing requirements, but they "would be subject to reimbursement obligations to persons who actually conduct the testing . . . ." <sup>24</sup>

Not having to conduct costly testing is a good thing. Being subject to the vagaries of cost reimbursement, however, would mean considerable uncertainty and potential expense — both of which could pose formidable deterrents to recycling activities. This is especially true under TSCA, where data compensation is a new and uncharted area.

## ***Market Realities and the Future of Voluntary TSCA Commitments***

The proposed SNURs reflect US EPA's sensitivity to market realities and its desire to prevent the re-introduction of PBDEs that domestic producers have agreed to phase out through voluntary measures. Eliminating the article exemption means that PBDEs cannot obtain a "free ride" back into the United States market via imported articles.

This provision rewards companies that have taken commercial steps they were not required to take. Such an expansive interpretation of the Agency's TSCA authority may also encourage similar voluntary commitments from others in the future.

## ***Unintended Consequences***

At the same time, US EPA will need to review the comments it receives on the PBDEs SNUR proposal carefully to avoid unintended consequences. In particular, the Agency should pay close attention to the issue of PBDE recycling.

US EPA may need to exempt recycling activities from the definition of processing in order to avoid imposing section 4 cost-reimbursement obligations on entities that should not be saddled with such burdens. Imposing these costs could discourage otherwise environmentally beneficial reclamation activities.

## ***Additional Considerations***

Stakeholders need to be mindful that publication of these proposed SNURs triggers reporting requirements for exports under TSCA section 12(b). Note, however, that export of SNUR chemicals in articles does not require TSCA section 12(b) export notification despite US EPA's proposal to invalidate the article exemption.

In the PBDEs SNUR proposal, US EPA has also confirmed that the general exemption from TSCA section 13(b) import certification is unchanged despite the elimination of the exemption for article importers and processors with respect to PBDEs.

## ***TSCA Creativity***

The SNUR proposals discussed in this column reflect a creative approach to TSCA. They also signal a renewed willingness on the part of US EPA to move forward on enhanced chemical management, with or without

legislative action on TSCA.

Can the aging canine that is TSCA learn some new maneuvers? We'll find out in the months and years ahead.

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**Lynn L. Bergeson** is managing principal of Bergeson & Campbell, P.C. (B&C), a Washington, D.C. law firm focusing on conventional, nanoscale, and biobased industrial, agricultural, and specialty chemical product regulation and approval matters, environmental health and safety law, chemical product litigation, and associated business counseling and litigation issues. She is President of The Acta Group, with offices in Washington, D.C., Manchester, UK, and Beijing, China, and President of B&C Consortia Management, L.L.C. (BCCM) with offices in Washington, D.C.

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## Notes

<sup>1</sup> The August 2011 document, entitled "Discussion Guide: Background and Discussion Questions for Identifying Priority Chemicals for Review and Assessment," describes a new approach to identifying priority chemicals for review and assessment under TSCA, inviting public input. The discussion guide outlines the Agency's chemical prioritization goals, describes its planned process for determining priority chemicals for review (including prioritization factors and data sources), and presents an overview on how certain chemicals will be selected from the priority list for assessment. US EPA will use a two-step process to identify priority chemical substances for review and assessment under TSCA. In step 1, the Agency plans to identify an initial group of priority chemicals for review by using a specific set of data sources to pinpoint chemicals that meet one or more action-plan priority factors. In step 2, US EPA intends to refine that group by using a broader range of data sources to analyze further and select specific chemicals from the initial group for additional assessment. The Agency is seeking input on the data sources to be used for further analysis in step 2.

<sup>2</sup> As noted in the Agency's "TSCA Work Plan Chemicals: Methods Document," the seven chemicals currently being assessed are: antimony and antimony compounds; HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[g]-2-benzopyran); long-chain chlorinated paraffins; medium-chain chlorinated paraffins; methylene chloride; n-methylpyrrolidone (NMP); and trichloroethylene. In conducting these risk assessments, US EPA will use information available through the data sources cited in the methods document, as well as other sources. According to the Agency, it "anticipates" issuing draft risk assessments for public review and comment as they are completed. If an assessment indicates significant risk, US EPA states that it will evaluate and pursue appropriate risk reduction actions as warranted. If an assessment indicates no significant risk, the Agency will conclude its current work on that chemical. Over time, US EPA will add additional chemicals to the work plan as more data are developed and more chemicals screened.

<sup>3</sup> US EPA (2012, April 2). Certain polybrominated diphenylethers; Significant new use rule and test rule, 77 Fed. Reg. 19862-19899.

<sup>4</sup> US EPA (2012, March 26). Significant new use rule for hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane, 77 Fed. Reg. 17386-17394.

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<sup>5</sup> US EPA (2012, March 28). Benzidine-based chemical substances; Di-*n*-pentyl phthalate (DnPP); and alkanes, C<sub>12-13</sub>, chloro; proposed significant new use rules, 77 Fed. Reg. 18752–18766.

<sup>6</sup> 40 C.F.R. section 721.25(a).

<sup>7</sup> Codified at 15 U.S.C. sections 2604(e), 2604(f), 2605, and 2606.

<sup>8</sup> TSCA section 5(g), codified at 15 U.S.C. section 2604(g).

<sup>9</sup> 77 Fed. Reg. at 19869 (col. 2).

<sup>10</sup> Codified at 40 C.F.R. section 721.10000.

<sup>11</sup> *Ibid.* The SNUR applies to any manufacture or import commenced on or after January 1, 2005. The PBDEs covered under the existing SNUR are: tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, and nonaBDE, or any combination of these chemical substances resulting from a chemical reaction.

<sup>12</sup> 40 C.F.R. section 721.45(f).

<sup>13</sup> 77 Fed. Reg. at 19863 (col. 3).

<sup>14</sup> *Ibid.*

<sup>15</sup> *Ibid.* at 19862.

<sup>16</sup> *Ibid.* at 19873-74.

<sup>17</sup> *Ibid.* at 19876.

<sup>18</sup> *Ibid.* at 17386-17387.

<sup>19</sup> Codified at 40 C.F.R. section 721.1660

<sup>20</sup> 77 Fed. Reg. 18753–18754.

<sup>21</sup> *Ibid.* at 19872 (col. 1).

<sup>22</sup> On May 21, 2012, US EPA announced an extension to the comment period for the PBDEs SNUR proposal. The comment deadline is July 31, 2012.

<sup>23</sup> 77 Fed. Reg. at 19865 (col. 3).

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<sup>24</sup> Ibid. at 19876 (col. 2).