

Washington Watch

TSCA Reform: Legislative Action Begins

Congress considers sweeping changes that could transform how chemicals are managed in the United States

Lynn L. Bergeson

On April 15, 2010, Senator Frank R. Lautenberg (D-NJ) released the text of the Safe Chemicals Act of 2010, S. 3209 (SCA),¹ which is intended to address the “core failings” of the Toxic Substances Control Act (TSCA).

On the same day, Representatives Bobby Rush (D-IL), Chairman of the House Subcommittee on Commerce, Trade, and Consumer Protection, and Henry Waxman (D-CA), Chairman of the Energy and Commerce Committee, released a discussion draft of their legislation, the Toxic Chemicals Safety Act of 2010 (referred to here as the Discussion Draft).² A discussion draft is a document that reflects ideas for new legislation. It is considered very much a work in progress intended to encourage discussion.

The Senate bill and House Discussion Draft suggest the type of top-to-bottom restructuring of domestic chemical management that is likely to become part of a new and “modernized” TSCA. As the discussion below reveals, there is nothing modest about the changes that are being proposed. The sweeping reforms that could become part of the legislative mix are nothing short of breathtaking.

This “Washington Watch” column begins with some background on TSCA and then previews the reforms that Congress will be considering. It notes the implications of TSCA reform for regulators and suggests how current regulatory efforts may affect the outlook for legislation.

Background: TSCA and Its Perceived Shortcomings

TSCA has been the subject of robust and often partisan controversy for years. Many in the chemical production and processing community believe the statute has worked fairly well, particularly when addressing new chemicals. But in the public health and environmental activist communities, many believe TSCA has worked poorly and needs significant reform. Virtually all stakeholders agree that the public’s confidence in the ability of the United States Environmental Protection Agency (US EPA) to protect human health and the environment under TSCA has eroded.

There are several key concerns with TSCA that are noted with great regularity. Specifically, detractors argue the following:

- Under the current TSCA statute, the burden of proof is misplaced. Chemical producers should have the burden of demonstrating that their chemicals are safe. Instead, the government is required to prove that a particular chemical is unsafe before it can take meaningful action to control the chemical’s sale and use.
- The legal standard for demonstrating that a chemical is likely to cause harm to human health or the environment is too burdensome and the evidentiary standard is too rigorous. These hurdles prevent US EPA from banning chemicals that it believes pose unreasonable risk.

- Chemical manufacturers and processors assert confidential business information (CBI) claims too frequently. As a result, too much information on chemicals is shielded from public disclosure.

As discussed below, the Senate bill and the House Discussion Draft offer dramatic changes to TSCA to address these and other concerns.

Key Legislative Changes Under Consideration

The following paragraphs summarize some important proposed changes to TSCA as reflected in the Senate and House legislation. The provisions described below are taken largely from the House Discussion Draft. Unless noted otherwise, the Senate's SCA includes similar provisions. Key differences between the bills are noted where relevant.

Both the Senate and the House proposals for TSCA legislative reform are quite lengthy. The summary of proposed changes offered here is not intended to be all-inclusive. In the space available in this column, it is not possible to do more than highlight several of the most important provisions.

TSCA Definitions

The Discussion Draft amends several existing TSCA definitions and proposes several new ones. Here are a few key definitional reforms.

■ ***“Chemical Substance” and “New Chemical”***

Both bills broaden the current definition of “chemical substance” to include a “chemical substance contained in or formed into an article.” Both measures also change the definition of “new chemical” to include substances for which the manufacturer or processor of the chemical substance has not submitted a declaration. (The requirements regarding declarations under the new law are discussed later in this column).

■ ***Confidential Business Information***

Importantly, with regard to the treatment of CBI, both measures change the definition of “health and safety study” to encompass “the specific chemical identity of the chemical substance or mixture.” This would make it difficult for a manufacturer or processor to claim that the chemical identity of a substance is CBI (such claims have been possible under current law).

It should be noted that US EPA is not waiting for legislative action to tighten up on the TSCA CBI rules in this area. On May 27, 2010, the Agency issued a notice advising stakeholders that, effective immediately, it would “begin a general practice of reviewing confidentiality claims for chemical identities in health and safety studies, and in data from health and safety studies, submitted under” TSCA.³ US EPA takes the position that TSCA section 14(b) does not extend CBI treatment to health and safety studies that, if made public, would not disclose:

- processes used in the manufacturing or processing of a chemical substance or mixture, or
- in the case of a mixture, the release of data disclosing the portion of the mixture

comprised by any of the chemical substances in the mixture.

The notice goes on to state, "Where a chemical identity does not explicitly contain process information or reveal portions of a mixture, EPA expects to find that the information would clearly not be entitled to confidential treatment."⁴

■ ***"Adverse Effect"***

Under the proposed legislation, "adverse effect" is defined broadly to include both more traditional TSCA-type effects and related exposures through food sources. The Discussion Draft changes the definition of the term to include "a chemical or biochemical change, anatomic change, or functional impairment, or a known precursor to such a change or impairment that:"

- affects or alters the performance of an anatomic structure of a vital system of an organism or progeny of an organism;
- causes irreversible change in the homeostasis of an organism;
- increases the susceptibility of an organism or progeny of an organism to other chemical or biological stressors or reduces the ability of an organism or progeny of an organism to respond to additional health or environmental challenges; or
- affects, alters, or harms the environment such that the health of humans or other organisms is directly or indirectly threatened.

This definition is expansive. It tends to make any "effect" an "adverse" one, and thus subject to TSCA reporting.

Chemical Testing and Minimum Data Sets

TSCA section 4 currently authorizes US EPA to promulgate rules requiring manufacturers, importers, and processors to test certain new or existing chemical substances or mixtures for their effects on human health and the environment. But there is no current requirement compelling the submission of data on all chemical substances and mixtures.

Both legislative measures now under consideration would require manufacturers and processors to submit a "minimum data set" (MDS) to the Agency. A MDS would have to include information on "substance characteristics and on hazard, exposure, and use of chemical substances and mixtures that [US EPA] anticipates will be useful in conducting safety standard determinations" or carrying out any other provision of the act.

Importantly, the Discussion Draft imposes the MDS requirement on both chemical substances and mixtures, while the Senate bill limits the requirement to "chemicals." Further, the House version would amend the definition of "mixture" to include articles ("any mixture contained in or formed into an article"), which would suggest that article mixtures would be subject to the MDS requirement.

Within one year of enactment of the Toxic Chemicals Safety Act of 2010 (TCSA), US EPA would be required to issue a rule setting forth what exactly must be included in a minimum data set. Manufacturers of new chemicals would be required to include the

required data when submitting a pre-manufacture notice (PMN). For existing chemicals, companies would be required to submit data within five years of enactment of the new law, or within 18 months of being listed on the section 6(a) "priority list" (discussed below).

Many believe the MDS requirement could severely frustrate development of new chemical products. Under the MDS provision, makers of new chemicals would be required to submit data as a condition of marketing their substances, while manufacturers of existing chemicals would have years to generate the same data set.

Requests for Information from Other Federal Agencies

The Discussion Draft includes a new provision not currently in TSCA regarding requests for information from other federal agencies to US EPA. Under the provision, if another federal agency determines that information relating to a chemical substance or mixture (including data from new testing or monitoring) would assist it in carrying out its duties, but the information is not available to the agency, then that agency can ask US EPA to seek the information on its behalf.

This sweeping provision would appear to offer broad authority to all federal agencies (via US EPA) to ask for just about anything in the way of information on chemical substances or mixtures.

New Chemical Substances and New Use Review

Under TSCA, manufacturers and importers must submit a PMN before manufacturing or importing any new chemical substance (meaning any substance that is not already listed on either the public or the confidential versions of the TSCA Inventory and that is not eligible for an exemption from PMN requirements). The PMN form seeks information on the identities of the submitter and the chemical substance, along with data on production volume, uses, exposures, and environmental fate.

TSCA does not require a submitter to test a new chemical substance before submitting a PMN. The submitter must, however, include with the PMN any health and safety data relating to the new chemical substance's health or environmental effects that are in its possession or control. US EPA also has certain authorities to require testing in connection with PMNs. Currently, TSCA includes statutory exemptions from the PMN requirement (e.g., for R&D and test marketing), as well as regulatory exemptions (e.g., under section 5(h)(4) for low-volume chemicals and polymers).

■ *PMN Changes*

Both the Senate bill and the House Discussion Draft would extend the PMN requirement to chemical processors (TSCA now limits it to manufacturers and importers). The Discussion Draft would also make several changes related to the submission and review of PMNs:

- submitters would be required to include a MDS along with the PMN;
- the PMN requirement would be extended to "new mixtures;" and
- no person would be allowed to manufacture or process a new chemical substance or mixture (or an existing chemical substance or mixture for a purpose that US EPA has

determined to be a new use) unless the Agency, based on a review of the PMN, finds that the substance or mixture (or its new use) is not reasonably anticipated to present a risk of injury to health or the environment, or unless the manufacturers and processors have established that the anticipated use of the chemical substance or mixture meets the safety standard established under section 6(b) (this safety standard is further discussed below);

- if the new chemical substance or mixture or the new use is reasonably anticipated to present a risk of injury to health or the environment, US EPA must complete a safety standard determination within six months; it should be noted that the standard enunciated here (“reasonably anticipated to present a risk of injury to health or the environment”) is broader than the current standard, which requires US EPA to determine that a substance “may present an unreasonable risk of injury to health or the environment.”

■ ***Exemption Provisions***

Both the Senate bill and the Discussion Draft include exemptions for test marketing, equivalent chemical substances, substances manufactured or processed in small quantities, and substances that exist temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and to which there is no (and will not be any) human or environmental exposure.

Neither the Senate bill nor the Discussion Draft includes the current section 5(h)(4) regulatory exemption provision. This means that substances currently in commerce based on exemptions under this section would be subject to the various requirements discussed above, including those related to PMNs and MDSs.

■ ***SCA Provisions on New Uses of Existing Chemicals***

With respect to a new use of an existing chemical that meets the safety standard, the Senate’s SCA would prohibit the manufacture or processing of the chemical substance “for a use, at a production volume, or in a manner other than those” that US EPA has specified in its safety determination unless certain conditions are met:

- the manufacturer or processor submits a notice of intention to manufacture or process the substance “for the new use, at the new production volume, or in such other manner that is inconsistent with a specified condition or term for such substance” and updates its MDS accordingly;
- the notice indicates that the chemical substance will continue to meet the safety standard if the allowed uses, allowed production volume, or other specified conditions or terms are revised to encompass the changes detailed in the notice; and
- US EPA determines that the manufacturer or processor submitting the notice has established that the chemical substance will continue to meet the safety standard if the allowed uses, allowed production volume, or other specified conditions or terms are revised to encompass the changes detailed in the notice.

Provided these conditions are satisfied, US EPA would amend the safety determination to include the new use or new production volume among the allowed uses or production volumes for the chemical substance.

Under the Senate SCA, after receiving the notice and supporting data, the Agency would have 180 days to determine whether the manufacturer or processor has established that the chemical substance will meet (or continue to meet) the applicable safety standard. US EPA could extend this deadline by one or more additional periods, not to exceed 12 months in the aggregate.

Priority List of Chemicals

The Discussion Draft includes a new provision that would require US EPA to develop a priority list including at least 300 chemical substances and mixtures for which safety standard determinations must be made first. The Agency would have to publish this list within 18 months after enactment of the new law.

In creating the list, US EPA would exercise its discretion based on available scientific evidence and consideration of the relative risk of chemical substances and mixtures, as well as their “presence in biological and environmental media, use, production volume, toxicity, persistence, bioaccumulation, or other properties indicating risk.”

Once a chemical substance or mixture is on the list, the Agency could remove it only after making a safety determination. US EPA would have to update the list periodically, adding chemical substances and mixtures so that the list never has fewer than 300 chemical substances and mixtures, “until such time as all chemical substances and mixtures in commerce have had a safety determination.” The Agency could make additions to the list based on petitions from citizens or recommendations from the Interagency Testing Committee (ITC).

The Senate SCA does not include a reference to the ITC (which exists now under TSCA), but would instead create a new Interagency Prioritization and Testing Committee (IPTC). The IPTC would maintain its own list of recommendations for the priority list, which it would update annually. The makeup of the IPTC would remain the same as that of the ITC, with each of the following agencies appointing one member from among its officers or employees: US EPA; US Department of Labor; Council on Environmental Quality; National Institute for Occupational Safety and Health; National Institute of Environmental Health Sciences; National Cancer Institute; National Science Foundation; and US Department of Commerce.

Safety Standard Determinations

The Discussion Draft includes a provision requiring US EPA to apply a safety standard that “takes into account aggregate and cumulative exposure to a chemical substance or mixture and that provides a reasonable certainty of no harm, including to vulnerable populations, and protects the public welfare from adverse effects, including adverse effects to the environment.”

Manufacturers and processors would have the burden of proving that their chemical substances or mixtures meet this safety standard. After they submit all the information necessary to make this determination, US EPA would have six months to decide whether the manufacturer or processor has met its burden of proof. The Agency’s safety determinations would remain in effect for 15 years, unless a new use of the chemical substance or mixture is proposed or new information on it warrants a redetermination.

The Senate’s SCA repeatedly references the “safety standard under section 6(b)” and “the applicable safety standard,” but it does not include language specifying what the safety

standard should be. Significantly, under the SCA, a determination by US EPA that a manufacturer or processor has failed to establish that a chemical substance meets the safety standard would not be subject to judicial review.

Both the Discussion Draft and the Senate SCA provide for renewing safety determinations. With respect to renewal, the SCA would require manufacturers and processors to submit a MDS for their chemical substance and indicate whether the substance (including any specified use to be evaluated and any proposed condition on the specified use) meets the safety standard. This submission would be required within 15 years after the date of the manufacturer or processor's previous information submission.

Managing Chemical Risks

Under the current TSCA section 6, US EPA is authorized to restrict or ban the manufacture, processing, or distribution in commerce of chemical substances or mixtures upon a showing that the activity "presents or will present an unreasonable risk of injury to health or the environment." The Agency must select the "least burdensome" option available to achieve its regulatory objectives. US EPA has exerted its TSCA section 6 authority sparingly and has never successfully used this provision to ban a substance.

Under the new safety determination provisions contained in the Discussion Draft, the Agency would assess significantly more chemicals for safety. It would also have greater discretion to take action on substances and mixtures that it determines do not meet the safety standard.

■ *Failure to Meet the Safety Standard*

Under the Discussion Draft, if US EPA determines that the safety standard has not been met for a new chemical substance or mixture or a new use, then that chemical substance or mixture could not be manufactured, processed, or distributed in commerce.

If the Agency determines that the safety standard has not been met for an existing chemical substance, then that chemical substance or mixture could not be manufactured, processed, or distributed in commerce effective one year after publication of the determination.

■ *Imposing Conditions to Ensure the Safety Standard Is Met*

The Discussion Draft specifies some actions US EPA can take if it finds that conditions must be imposed to ensure that a chemical substance or mixture meets the applicable safety standard. Among other options, the Agency can:

- prohibit the manufacture, processing, or distribution in commerce of a chemical substance or mixture, or a particular use of a substance or mixture;
- limit the amount that can be manufactured, processed, or distributed in commerce with respect to a chemical substance or mixture or a particular use of the substance or mixture,
- require warnings and instructions with respect to the use, distribution in commerce, and disposal of a chemical substance or mixture;

- impose recordkeeping requirements;
- prohibit or limit any manner or method of disposal; and
- require development of a risk reduction management plan to achieve any risk reduction measure required by the Agency.

■ ***Quality Control Orders***

Under the Senate SCA, if US EPA has a “reasonable basis” to conclude that a chemical substance or mixture is being manufactured or processed in a manner that may present a substantial endangerment to health or the environment, the Agency could by order require the manufacturer or processor to submit a description of the quality control procedures being followed.

If US EPA determines that these quality control procedures are inadequate to prevent the chemical substance or mixture from presenting a risk of injury, the Agency could order the manufacturer or processor to revise the quality control procedures to the extent necessary to remedy the inadequacy.

If US EPA determines that past quality control procedures have resulted in the distribution in commerce of a chemical substance or mixture that may present “a substantial endangerment to health or the environment,” the Agency could order the manufacturer or processor to give notice of the endangerment to processors and/or distributors, and (to the extent reasonably ascertainable) to “any other person in possession of or exposed to the substance or mixture.” In addition, the Agency could order the manufacturer or processor to give public notice of the endangerment and provide for the replacement or repurchase of the substance or mixture “as is necessary to adequately protect health or the environment.”

■ ***Time-Limited Exemptions***

Both the Senate SCA and the House Discussion Draft would authorize US EPA to issue certain specific, time-limited exemptions from restrictions on the use of chemical substances. The Discussion Draft calls these “critical use exemptions,” while the SCA refers to them simply as “exemptions.”

The Agency could exempt a specific use of a chemical from a restriction for a period not to exceed five years (renewable for one or more additional five-year periods) if the manufacturer or processor demonstrates by “clear and convincing evidence” that:

- the exemption is in the “paramount interest of national security”;
- the restriction would significantly disrupt the national economy; or
- the specific use is a critical or essential use and (i) no feasible safer alternative for the specified use is available or (ii) the specified use of the chemical substance or mixture provides a net benefit to health or the environment when compared to all available alternatives.

These bases for seeking an exemption are extremely narrow. As a result, few (if any) exemption requests would be likely to qualify.

US EPA would be required to provide the public with notice of any exemption granted, while manufacturers and processors would have to notify known purchasers of the chemical substance or mixture.

Reporting Requirements

■ ***Declarations by Manufacturers and Processors***

Both bills propose a new reporting requirement for chemical manufacturers and processors. Within one year after the new law is enacted, each manufacturer or processor of a chemical substance or mixture distributed in commerce would have to provide a "declaration" to US EPA.

If the submitter is currently manufacturing or processing the chemical substance or mixture (or will be doing so), the declaration would include:

- the chemical identity of the chemical substance or mixture;
- data about where manufacture, processing, and distribution occurs;
- a list of existing health and safety studies related to the chemical substance or mixture, along with copies of any that have not previously been submitted to US EPA; and
- "all other information known to, in the possession or control of, or reasonably ascertainable by the manufacturer that has not previously been submitted to" US EPA regarding the physical, chemical, and toxicological properties of the chemical substance or mixture; annual production volumes, known uses, and exposure data; and the name and location of each facility to which the chemical substance or mixture is sent, after manufacture or processing, for subsequent processing, distribution, or use.

If the submitter no longer manufactures or processes a chemical substance or mixture (or will stop doing so within 180 days of submission), then the submitter would provide a "declaration of cessation of manufacturing or processing." The submitter would have to certify cessation of "all production, importation, processing, and export of the chemical substance or mixture."

Active manufacturers and processors would have to update their declarations at least every three years or "immediately" if there is

significant new information regarding a physical, chemical, toxicological property or use of, or exposure to, the chemical substance or mixture, including any information that demonstrates a potential new adverse effect of the chemical substance or mixture, corroborates previous information demonstrating or suggesting an adverse effect, or suggests an adverse effect at a lower dose than previously demonstrated.

■ ***Inventory of Chemicals***

The House Discussion Draft would require that all chemical substances and mixtures in commerce be included and maintained on the Inventory. Under the Senate SCA, the

Inventory would include each chemical substance that is manufactured or processed and, pursuant to new section 8(c)(2), the list would have to encompass chemicals entering commerce, as well as chemicals on which US EPA has requested reports under new section 8(b).

■ ***Required Reporting of Information Deemed Necessary by US EPA***

Under proposed SCA section 8(b), US EPA could require reporting of any information the Agency deems necessary for making safety determinations or otherwise administering the SCA's provisions. This section does not reference the declarations discussed above, which would be required under section 8(a) of the SCA bill.

Standards for CBI Claims and Disclosure of Information

Consistent with Congress's promise to address a "core failing" of TSCA, both the Senate and House measures would greatly narrow the grounds for asserting CBI claims. Currently, TSCA section 14(a) prohibits US EPA (except in certain limited circumstances) from disclosing trade secrets and commercial or financial information that is privileged or confidential.

Under the House Discussion Draft, US EPA would be required, within one year of the law's enactment, to publish standards that specify "the acceptable bases on which designations" of CBI could be made. The Discussion Draft sets forth certain categories of information that would not be eligible for confidential protection. These categories include:

- chemical identity "except as provided in section 5" (it should be noted that there is no relevant discussion on CBI treatment of chemical identity in section 5 of the Discussion Draft, so it is not clear what this provision may be referencing);
- any safety standard developed under section 6(b), including any supporting information developed by US EPA;
- any health and safety study (recall that the definition of "health and safety study" would be revised to include chemical identity information) submitted under this law with respect to (i) any chemical substance or mixture that has been offered for commercial distribution or for which testing has been required under section 4 or notification required under section 5, and (ii) any data reported to or otherwise obtained by US EPA from a health and safety study that relates to such a chemical substance or mixture; and
- any information indicating the presence of a substance or mixture in an article intended for use or reasonably expected to be used by children, or to which children can otherwise be reasonably expected to be exposed.

The Discussion Draft specifies that if a confidential designation is denied, US EPA would have to make the information available to the public. If a confidential designation is approved, the Agency would be required to specify a time period (not greater than five years) during which the information would be kept confidential.

The Discussion Draft also includes a new provision on "risk information for workers." It would require US EPA to provide standards for, and facilitate the sharing of, certain information with workers who may be exposed to, or come in contact with, chemical

substances in the course of their employment. The types of information covered by this provision would include data on chemical identities, safety determinations, and health and safety impacts.

Preemption Issues

Much of the debate around TSCA reform has focused on the need to modernize the law so that state and local entities will no longer seek to address TSCA's failings on their own. Such state and local laws can often complicate the interstate marketing, sale, and distribution of chemical products. Interestingly, however, neither the Senate nor the House bill contains provisions that would clearly address the concerns that chemical manufacturers and distributors have on this topic.

Current TSCA section 18 preempts states and their political subdivisions from enacting requirements applicable to a chemical substance or mixture that is regulated under TSCA section 5 or 6, unless the state requirement is identical to the federal requirement, implements another federal law, or prohibits use of the substance or mixture within the state. A state or political subdivision may ask US EPA to allow it to adopt a requirement that provides a significantly higher degree of protection from risk than does the federal requirement.

Under the House Discussion Draft, states and political subdivisions would have the power to adopt or enforce requirements that are different from or in addition to requirements established under the new TSCA, unless compliance with both TSCA and the state or political subdivision requirement would be "impossible."

The Senate bill states that neither the SCA, nor any rule, regulation, or order issued or promulgated pursuant to the SCA, would "preempt, displace or supplant any provision of any law, including common law, of any State or political subdivision of a State relating to any chemical substance or mixture, or any article that contains a chemical substance or mixture, which is more stringent than is provided for under this chapter."

Risk Assessment for Persistent and Bioaccumulative Chemicals

The House Discussion Draft proposes a new section 32 entitled "Risk Assessment for Chemical Substances and Mixtures That Are Persistent and Bioaccumulative." The Senate SCA does not include a similar provision.

The new section 32 would require US EPA to establish a methodology for evaluating the risks posed by chemical substances and mixtures that are determined to be persistent and bioaccumulative. The Agency would have to promulgate this methodology within one year after enactment of the new law.

US EPA would be required to review each chemical substance and mixture on the section 6(a) priority list (discussed above) to determine whether it is persistent or bioaccumulative. For those that are so identified, the Agency would have to conduct safety standard determinations in accordance with the methodology it has established.

US EPA also would be authorized to take action under section 6(c) as necessary to ensure that the manufacturing, processing, distribution in commerce, use, and disposal of any chemical substance or mixture identified as persistent or bioaccumulative meets the applicable safety standard.

Expedited Action for Certain Chemical Substances

The House Discussion Draft proposes a new section 33 entitled “Expedited Action for Chemical Substances with Documented Risks.” The section refers to chemical substances “for which risk[s] to health or the environment have been well documented yet sufficient risk management actions have not been taken” and specifically lists over 30 chemical substances. Included on the list are asbestos, bisphenol A, formaldehyde, methylene chloride, certain perfluorinated compounds, certain phthalates, and vinyl chloride. The actual number of chemicals covered by this section could be in the hundreds since the list also encompasses some chemical compounds.

US EPA would be required to take “expedited action” on the listed chemical substances within one year of the new law’s enactment. The Agency would have to determine whether manufacturers and processors of each listed chemical have established that their substances meet the applicable safety standard. US EPA would also be required to take “appropriate action” to ensure that the chemical substances and mixtures meet the safety standard.

Manufacturers and processors of identified chemical substances and mixtures would not immediately be required to submit a MDS, but they would have to submit the declaration required by the new provision in section 8 within six months after enactment of the new law in order to inform US EPA’s determinations under this section.

Pursuant to the new section 33, no person would be allowed to manufacture or process an “expedited list” chemical substance or mixture for a new use, except for those specifically exempted under section 6(e) of the new law and in accordance with a redetermination process in new section 6(b)(5).

The Senate SCA includes a section regarding “expedited action on chemicals of highest concern.” It does not identify any specific chemicals, however. Instead, the section states only that US EPA “shall act quickly to manage risks from chemical substances that clearly pose the highest risks to human health or the environment.”

Children’s Environmental Health Initiatives

The Discussion Draft includes a new section 34 that would require US EPA to establish a Children’s Environmental Health Research Program within 90 days of enactment of the new law. The purpose the program would be to further understanding of the vulnerability of children to chemical substances and mixtures.

The Agency would also be required to create an Interagency Science Advisory Board on Children’s Health and Toxic Substances within the same 90-day period. This board would provide independent advice, expert consultation, and peer review on scientific and technical issues related to protection of children’s health under the new law.

Reduction in Animal-Based Testing

The Discussion Draft proposes a new section 35 that would require US EPA to minimize the use of animals in testing of chemical substances or mixtures. The Agency would be directed to encourage and facilitate, where practicable, the use of existing data, the use of test methods that eliminate or reduce reliance on animals, grouping of chemical substances for testing, formation of industry consortia to reduce testing redundancy, and parallel submission of data from both animal-based studies and emerging methods and

models. The Agency would also fund “research and validation studies to reduce, refine, and replace the use of animal tests.”

In addition, the Discussion Draft also proposes to establish an Interagency Science Advisory Board on Alternative Testing Methods. In consultation with US EPA, the board would help develop a strategic plan to promote alternative testing methods that do not rely on animals.

Developing Safer Alternatives to Existing Chemicals

The Discussion Draft proposes a new section 36 that would require US EPA to establish a program aimed at creating market and other incentives for the development of safer alternatives to existing chemical substances and mixtures. The program, which would be established within one year after enactment of the new law, would seek alternatives that reduce or avoid the use or generation of hazardous substances.

Under the program, a new chemical substance or mixture would be eligible for expedited review if the manufacturer or processor provides an “alternatives analysis” indicating that the chemical or mixture is a safer alternative to existing chemicals.

The program would also require US EPA to create other appropriate incentives and to recognize safer alternative chemical substances or products via the use of special marketing designations, public awards, and rewards. The Agency would be directed to promote the development of green chemistry through the use of grants, contracts, and other means.

Addressing Public Exposure to Toxic Chemicals in “Hot Spot” Localities

The Discussion Draft proposes a new section 39, which would address “hot spot” localities -- areas where residential populations are disproportionately exposed to toxic chemical substances and mixtures. Within 180 days after enactment of the new law, US EPA would be required to promulgate a rule that establishes criteria for defining disproportionate exposure and identifying localities where populations are disproportionately exposed.

Within 120 days thereafter, the Agency would be required to identify a list of localities with disproportionate exposure. The public would have an opportunity to “nominate” localities for inclusion. Within 180 days after creation of the list, US EPA would have to publish it. The list would be updated at least once every five years.

No later than one year after publishing the initial list, the Agency would be required to develop and publish action plans for reducing disproportionate exposure in every identified locality. Each plan would indicate the chemical substances and mixtures that contribute to the disproportionate exposure and describe actions that will be taken to reduce the exposure. Every plan would also include a percentage reduction goal for each identified chemical and a timeline for achieving that goal.

US EPA would be required to make an annual report to Congress that identifies the listed localities, includes the action plans, and describes the progress on each action plan to date. The report would be made available to the public.

The Senate SCA includes a provision similar to that contained in the House Discussion Draft. The Senate provision also includes an additional subsection stating that the following “hot spot”-related actions would not be subject to judicial review: US EPA

decisions to identify localities for inclusion on the disproportionate exposure list, decisions in response to locality nominations submitted by the public, and decisions to list localities or to update the list. By contrast, a failure on the part of US EPA to publish a list of localities or to update the list would be considered a failure to perform a nondiscretionary duty, and thus would be subject to judicial review.

Mission Impossible for US EPA?

As the discussion above indicates, the legislative changes to TSCA being considered by Congress are broad and deep. Both the Senate and the House bills address TSCA's much publicized "failures" in ways that are radically different from the current law. Both would add new provisions and create entirely new programs.

Both measures also would present some core problems for US EPA. The Agency would be held to impossibly tight timeframes and would be expected to complete Herculean tasks. Based on US EPA's decades of chemical management experience to date, it is clear that the Agency simply could not accomplish the range of tasks contemplated under these measures within the stated timeframes, even with the addition of significant new staff and resources.

Stakeholder Input on Proposed Legislation

These challenges were discussed in a series of stakeholder meetings on the Discussion Draft convened by the United States House of Representatives in April and May 2010. The meetings, which were attended by invited stakeholders, reportedly generated much dialogue and debate. In addition to expressing concerns about a range of issues, stakeholders also indicated support for some provisions of the draft, including diminished animal testing and promotion of green chemical products. All of this stakeholder input is thought to have been helpful in educating House staff on TSCA's complexities.

Legislative Action: Next Steps

As of this writing, the House was expected to introduce its bill sometime during the summer, and perhaps schedule hearings on it. Legislation is not expected to be considered in earnest in 2010, however.

US EPA Regulatory Activities: Making TSCA Legislative Reform Less Urgent?

As indicated earlier in this discussion, legislative reform is not the only type of legal change affecting chemical management in the United States. US EPA has also been making regulatory changes.

Increasing Information Availability

In particular, the Agency has taken several steps to curb CBI claims and make more information available to the public. For example, as discussed above, US EPA issued a notice on May 27 regarding confidentially claims for chemical identities in health and safety studies.

Earlier in the year, on January 21, 2010, the Agency also announced a new policy concerning CBI claims for chemical identities contained in "substantial risk" information submitted under TSCA section 8(e).⁵ Pursuant to the new policy, if a chemical substance is listed on the public portion of the TSCA Inventory, US EPA expects that a company

submitting information to the Agency under section 8(e) will not claim the chemical identity as confidential.

In a related non-TSCA action, last December the Agency announced its intent to increase the public availability of information on inert ingredients in pesticides.⁶ More disclosure of data on pesticide inert ingredients has long been a goal of some nongovernment organizations, and lack of disclosure in this area has been the subject of much debate.

Chemical Action Plans

Another significant regulatory program involves US EPA's development of chemical action plans (CAPs) for existing chemicals under TSCA. Last September, Administrator Lisa Jackson announced plans to strengthen the Agency's current chemical management program through the development of chemical action plans.⁷ US EPA's initial list of chemicals to be considered for CAPs included benzidine dyes and pigments, bisphenol A (BPA), polybrominated diphenyl ethers (PBDEs) in products, long-chain perfluorinated chemicals (PFCs), phthalates, and short-chain chlorinated paraffins (SCCPs).

On December 30, 2009, the Agency issued CAPs for phthalates, PFCs, PBDEs in products, and SCCPs. On March 29, it added an action plan for BPA. The Agency reportedly is working on a final action plan for benzidine dyes and pigments, and has announced that it will also be preparing action plans for nonylphenol/nonylphenol ethoxylates, hexabromocyclododecane, siloxanes, and diisocyanates. As of this writing, the next set of action plans was expected to be released in late summer 2010.

Dampening the Prospects for TSCA Legislative Reform?

Given the brisk pace of US EPA regulatory efforts, some might suggest that the urgent need for TSCA legislative reform has abated. If the Agency continues its string of regulatory developments on existing chemicals (most of which are being carried out pursuant to existing TSCA authority), Congress may be less motivated to make TSCA reform a legislative priority.

It is unlikely that Congress will abandon legislative reform entirely, however, given that the momentum for TSCA statutory overhaul has been growing for years. Such an outcome also might not be in the best long-term interests of the chemical community, given the erosion of the public's trust in TSCA generally.

In the short term, however, US EPA's regulatory measures could well temper Congressional zeal for legislative action. Especially with all the urgent legislative matters now crowding Congress's already-congested calendar, the Agency's actions could help move TSCA legislative reform off the front burner -- back to where it has been for longer than many care to admit.

Lynn L. Bergeson is managing director of Bergeson & Campbell, P.C., a Washington, D.C. law firm focusing on conventional and engineered nanoscale chemical, pesticide, and other specialty chemical product approval and regulation, environmental health and safety law, chemical product litigation, and associated business issues, and president of The Acta Group, L.L.C. and The Acta Group EU, Ltd with offices in Washington, D.C. and Manchester, UK.

Notes

¹ Available online at <http://lautenberg.senate.gov/assets/SCA2010.pdf>

² Available online at http://energycommerce.house.gov/Press_111/20100415/TCSA.Discussion.Draft.pdf

³ US EPA (2010, May 27). Claims of confidentiality of certain chemical identities contained in health and safety studies and data from health and safety studies submitted under the Toxic Substances Control Act, 75 Fed. Reg. 29754-29757.

⁴ *Ibid.* at 29754.

⁵ US EPA (2010, January 21). Claims of confidentiality of certain chemical identities submitted under section 8(e) of the Toxic Substances Control Act, 75 Fed. Reg. 3462-3463.

⁶ US EPA (2009, December 23). Public availability of identities of inert ingredients in pesticides, 74 Fed. Reg. 68215-68223.

⁷ See US EPA, Existing Chemicals Action Plans web site, <http://www.epa.gov/oppt/existingchemicals/pubs/ecactionpln.html>