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The Devilish Details Of TSCA Reform

Law360, New York (April 27, 2011) -- On April 14, Sen. Frank R. Lautenberg, D-N.J., introduced the Safe Chemicals Act of 2011, which is intended to modernize the Toxic Substances Control Act to require chemical companies to demonstrate the safety of industrial chemicals and the U.S. Environmental Protection Agency to evaluate safety based on the best available science.

The bill is co-sponsored by Sens. Amy Klobuchar, D-Minn., Charles Schumer, D-N.Y., and Barbara Boxer, D-Calif. Lautenberg introduced TSCA reform legislation in the 111th Congress, the Safe Chemicals Act of 2010 (S. 3209). In response to feedback from chemical industry leaders, public officials, scientists, doctors, academics and nonprofit organizations, Lautenberg states that he has made several changes to improve the bill. Below is a quick summary of key differences between Lautenberg's current bill and S. 3209.

Section 4: Definitions — *Section 3 of the TSCA has been revised as follows (numbers in parentheses identify the placement of the definitions discussed):*

- The definition for "adverse effect" in S. 3209 has been dropped although the term is still used, including in several definitions.
- "Aggregate exposure" (2) is defined to include all sources of exposure, including exposures derivative of non-TSCA uses (uses subject to the Federal Food, Drug, and Cosmetic Act (FFDCA), for example), notwithstanding that regulating cosmetic chemical exposures using TSCA has not been discussed over the years.
- "Bioaccumulative" (3) would be defined as "the chemical substance or mixture, as determined by the administrator, can significantly accumulate in biota, as indicated through monitoring data, or is highly likely to accumulate in biota, as indicated by other evidence." S. 3209 cross-referenced EPA's policy statement on "Persistent, Bioaccumulative and Toxic" (PBT) chemicals. The new requirement that the term include a chemical-specific determination (as opposed to meeting specific criteria as appeared in EPA's Policy Statement) seems to expand the possible meaning and to be tied to the way that PBTs are treated under Section 6 in the draft bill.
- "Chemical identity" (4) no longer includes provisions concerning mixtures, but see below where new Section 26(c)(3) grants EPA authority to extend authorities and requirements to mixtures if the administrator determines that "such extension is reasonable and efficient."
- "Chemical substance" (5) deletes the reference to "articles" that appeared in S. 3209 but retains the provision allowing the administrator to determine, notwithstanding molecular identity, that a variant of a chemical substance is a new chemical substance (of key significance to the nano community).
- "Cumulative exposure" (7) is defined to refer to aggregate exposures from multiple chemicals that "are known or suspected to contribute appreciably to the same or similar adverse effect" (the italicized text is an addition to the S. 3209 definition and has the effect of broadening the meaning, especially as "similar" adverse effects are not explicitly defined).
- "Distribute in commerce" (8) and "distribution in commerce" would be expanded to

include the export or offer for export of the substance, mixture, or article.

- "Environment" (10) would be defined to include "ambient and indoor air."
- A "new chemical substance" (15) would be defined as one "for which the manufacturer or processor of the chemical substance has not submitted a declaration" (the use of "the" has the effect of extending this requirement to each manufacturer or processor of the new chemical).
- "Persistent" (16) would be defined as "the chemical substance or mixture, as determined by the administrator, significantly persists in 1 or more environmental media, as indicated by monitoring data or other evidence."
- "Reasonable certainty of no harm" from S. 3209 is no longer included, although the term (slightly modified to "reasonable certainty that no harm will result") is still used in the Section 6 safety standard.
- "Special substance characteristic" has been retained, including considerations for size or size distribution; shape and surface structure; reactivity; and any other properties that may significantly affect the risks posed (again, of key significance to the nano community).

Section 5: Minimum Data Sets and Testing of Chemical Substances — *Section 4 of TSCA would be revised as follows:*

The minimum data set requirements have been revised and the bill would require a rule to be promulgated by the EPA that would:

- Require Minimum Data Sets (changed from "set") to include the minimum amount of information necessary for the administrator to conduct a "screening-level risk assessment of the chemical substance or category of chemical substances, including information on the characteristics, toxicological properties, exposure, and use of a chemical substance.
- "[E]ncourage and facilitate the use of alternative testing methods and testing strategies to generate information quickly, at low cost, and without the use of animal-based testing," including toxicity pathway-based risk assessment, in vitro studies, computational toxicology, high-throughput screening and related techniques.

Section 4(a)(2) would require "each manufacturer and processor" to submit the Minimum Data Set for the chemical — S. 3209 had required "the manufacturers and processors" to submit the Minimum Data Set. The effect of the change is seemingly to impose an individual requirement for submitting the Minimum Data Set on each manufacturer and processor, whereas S. 3209 could be read to impose a collective requirement on all manufacturers and processors.

- The Minimum Data Set on existing chemicals would be due within the earlier of 18 months after the date on which the substance is assigned to a Section 6 priority class, or five years after the date of enactment, whereas the Minimum Data Set would be required at the time of filing notifications for new chemicals.

Section 6: Manufacturing and Processing Notices — *Section 5 of the TSCA would be revised as follows:*

- Whereas S. 3209 had extended the new chemical notification requirements to mixtures, the revised bill has deleted mixtures from the requirements under Section 5. New Section 26(c)(3) authorizes the EPA to extend such requirements to mixtures.

Consistent with S. 3209, under Section 5(a)(1) a new chemical notification would be required of any person manufacturing or processing a new chemical.

Section 7: *Prioritization Safety Standard Determination and Risk Management — Section 6 of TSCA would be revised as follows:*

- The new bill would require the EPA to develop and publish a list that: (1) contains the names of the chemical substances or categories of chemical substances that the administrator determines warrant placement within one of three “priority classes”; and (2) identifies the priority class to which each listed chemical substance or category of chemical substances has been assigned by the administrator. Under S. 3209, prioritization was based on production volume, use, hazard, exposure information, etc.
- Consistent with S. 3209, the bill would prohibit judicial review of the assignment of a particular chemical substance; a determination by the administrator of whether a particular assignment is warranted; a response to a petition to include a particular chemical substance on the list; and the issuance of a recommendation to list a chemical substance.
- Under the act, the administrator “shall base the determination of whether the safety standard has been met solely on considerations of human health and the environment, including the health of vulnerable human populations.” In making a safety standard determination, the administrator shall: 1) to the extent practicable, review and incorporate any available scientific information relating to the effect of cumulative exposure to that chemical substance on human health and the environment; and 2) find that a chemical substance meets the safety standard only if there is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance. The proposed standard is similar to the one contained in the House bill (H.R. 5820) from the last Congress. The revised bill makes explicit that the standard is based “solely” on health and the environment and that the standard is met “only” if there is a reasonable certainty that no harm will result from aggregate exposure (as noted above in the Definitions section, the current bill does not include a definition for this term, whereas S. 3209 had defined “reasonable certainty of no harm”).
- Not later than five years after the date of enactment, and not less frequently than once every five years thereafter, the administrator shall review the methodology and may revise it to reflect new scientific developments or understandings. A determination by the administrator that a manufacturer or processor has not established that the chemical substance meets the applicable safety standard would not be subject to judicial review.
- The administrator would have one year after the earlier of the date of receipt of a complete submission or the applicable submission deadline, or after initiating a redetermination, to determine or redetermine, as appropriate, whether the manufacturers and processors have established that the chemical substance meets the safety standard.
- As for the burden of proof, manufacturers and processors of a chemical substance are to provide “sufficient information” for the EPA to determine whether the chemical substance meets the applicable safety standard.
- The EPA is to base safety determinations on the “best available science” and the administrator “shall base the determination on the recommendation of the National Academy of Sciences in the report ‘Science and Decisions.’” It is not clear how any conflict over this language would be resolved if the Academy or other authoritative body were to change its recommended approach over time.

Section 12: *Exports:*

- The current bill would add back the requirement for export notifications if a chemical is subject to data submission requirements. This would require export notifications on all chemicals (this seems to be the case because all chemicals, both new and existing, would seemingly be subject to the Section 4 Minimum Data Set, e.g., it is not clear that chemicals can be exempted from this requirement, although perhaps some flexibility can be found).

Section 13: *Entry into Customs Territory of the U.S.:*

- TSCA Section 13 would be amended to include an important new provision regarding import as part of an article: "Chemical substances and mixtures imported as part of an article shall be subject to the same requirements under this Act as if the substances and mixtures had been imported in bulk, except as the Administrator may provide by rule under this Act, or as the Secretary of Homeland Security may provide by rule." This requirement would thus apply all statutory obligations to such substances in imported articles (including, e.g., submission of a Minimum Data Set, new chemical notification, Section 8 declaration, etc.) unless and to the extent such requirements have been excluded by rule.

Section 14: *Disclosure of Data:*

- Under the bill, no later than one year after the date of enactment, the EPA administrator would identify by rule those types of information for which the administrator shall not prospectively specify the term of confidentiality.
- The provision allowing manufacturers, processors, or distributors to designate data believed to be entitled to confidential treatment does not limit the authority of the administrator to determine that particular information, previously considered entitled to confidential treatment, is no longer entitled to such treatment.
- The bill would amend TSCA to allow that, if the EPA administrator determines that the release of confidential data is necessary to protect against an "imminent and substantial endangerment to health or the environment," then no notice is required.
- The bill would clarify that Confidential Business Information (CBI) may be shared with state governments if "1 or more applicable agreements ensure that the recipient government will take appropriate steps to maintain the confidentiality of the information."
- The bill contains a catch-all provision that clarifies that the EPA may determine that certain information previously determined as eligible for CBI treatment is no longer subject to such protection.

Section 18: *Preemption:*

The provision has been rewritten and seemingly narrowed compared to S. 3209:

"Nothing in this Act affects the right of a State or a political subdivision of a State to adopt or enforce any regulation, requirement, or standard of performance that is different from, or in addition to, a regulation, requirement, liability, or standard of performance established pursuant to this Act unless compliance with both this Act and the State or political subdivision of a State regulation, requirement, or standard of performance is impossible, in which case the applicable provisions of this Act shall control."

Section 23: *Administration of the Toxic Substances Control Act:*

As noted above, the bill would amend TSCA Section 26(c) to add the following provision,

which would greatly expand the scope of the bill and the EPA's jurisdiction:

"Mixtures — Any action authorized or required to be taken by the Administrator or any other person under any provision of this Act with respect to a chemical substance is likewise also authorized or required with respect to a mixture, if the Administrator determines that such extension is reasonable and efficient."

Observations and Comments

The newly circulated language makes clear attempts to respond to industry's criticism of last year's proposal, and which was similarly levied against the companion House legislation. Examples include clarifying and limiting the purposes of the Section 4 Minimum Data Set to "screening level information" and separating out categories of Section 6 priorities and actions in lieu of blanket and encompassing data generation, assessment and safety standard determination requirements that S. 3209 applied to all chemicals.

The explicit Section 6 "hit list" is removed and left to a process where the EPA will evaluate the data and is to take action. The proposed bill also attempts to strike a more workable balance in its approach to preemption. The treatment of mixtures is greatly facilitated conceptually, but as noted, it remains potentially open-ended depending on the EPA definition of "reasonable and efficient" (and any decisions by the EPA in this regard would likely involve litigation over its scope by parties who believe it is either too broad or too narrow).

It is clear that the proposal introduces a number of significant new requirements and expansions in other requirements. One example is the treatment of "mixtures" as discussed above. Other examples include the requirements that: each manufacturer or processor of a chemical must submit a Minimum Data Set; that seemingly all chemicals would be subject to export notification; and that substances in imported articles must meet all statutory requirements unless the requirements have been excluded by rule.

As is often noted, "the devil is in the details," and even with a 182-page proposal, there are unclear elements about the proposal that will determine exactly what the scope, reach and impact of these amendments would be. At the same time, it is another set of specific amendments, re-drafted to respond to earlier criticisms, which should put more pressure on those in the chemical industry to respond with specific counter-proposals or an altogether alternative set of amendments.

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