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US HOUSE OF REPRESENTATIVES OVERWHELMINGLY APPROVES LANDMARK TSCA REFORM LEGISLATION

On June 23, 2015, by a vote of 398-1, the US House of Representatives (House) overwhelmingly approved HR 2576, the TSCA Modernization Act of 2015, a landmark bill that would significantly amend the decades-old Toxic Substances Control Act (TSCA).

The legislation approved by the full House is slightly different from the version voted on by the House Energy & Commerce (E&C) Committee on June 3. As approved by the House, HR 2576 makes a number of substantive changes to the existing TSCA law.

Regulatory Action on Chemicals

HR 2576 gives the US Environmental Protection Agency (EPA) greater ability to take regulatory action on chemicals under Section 6 of TSCA by eliminating the current TSCA requirement that EPA must select the "least burdensome" option for action after the agency has determined that a chemical presents or will present an unreasonable risk of injury to health or the environment under its intended conditions of use.

HR 2576 provides that, before restricting (or banning) a chemical substance, EPA must conduct a "risk evaluation" to determine whether the substance presents an unreasonable risk of injury.

If EPA determines that a chemical substance presents an unreasonable risk based on the risk evaluation (without consideration of costs or "other non-risk factors"), EPA would be required to issue a proposed rule setting forth regulatory action on the substance within one year after the risk evaluation is published, with the final rule to be issued within two years.

In promulgating a rule to restrict or ban a chemical substance or mixture under Section 6, EPA would have to "consider and publish" a statement that addresses "the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings" to it, as well as its effects on the environment and the magnitude of environmental exposure; the benefits of the substance or mixture; and the "reasonably ascertainable economic consequences" of the rule. Any restrictions imposed on a substance or mixture must be "cost-effective," except where EPA determines that additional requirements "are necessary to protect against the identified risk." EPA also must determine whether "technically and economically feasible alternatives" to the substance or mixture "will be reasonably available as a substitute."

HR 2576 provides that EPA must exempt any replacement parts designed before the Section 6 rule is promulgated unless EPA determines that the parts "contribute significantly to the identified risk, including identified risk to identified potentially exposed subpopulations." HR 2576 also limits EPA's ability to restrict articles by providing that it may do so "only to the extent necessary to protect against the identified risk" presented by a chemical substance or mixture in the article.

Risk Evaluations for Chemicals

HR 2576 provides that EPA will conduct a risk evaluation on a chemical substance if it determines that the substance may present an unreasonable risk because of potential hazard and a potential route of exposure under the substance's intended conditions of use. EPA is authorized to conduct risk evaluations of its TSCA Work Plan chemicals without having to first make such a determination, however. Additionally, HR 2576 requires EPA to conduct a risk evaluation of a chemical substance if the manufacturer of the substance requests that EPA do so, but the manufacturer must request the risk evaluation "in a form and manner prescribed" by EPA and must pay the cost of the risk evaluation.

In conducting a risk evaluation on a chemical substance, EPA would have to follow certain requirements for considering hazard and exposure data that are set out in the bill. EPA would be required to take into account "the likely duration, intensity, frequency, and number of exposures under the intended conditions of use" of the substance; describe "the weight of the scientific evidence for identified hazard and exposure;" and "consider whether the weight of the scientific evidence supports the identification of doses of the chemical substance below which no adverse effects can be expected to occur." EPA also would be required to "integrate and assess information on hazards and exposures for all of the intended conditions of use" of the substance, including "information on potentially exposed subpopulations." EPA is expressly prohibited from considering information on "cost and other factors not directly related to health or the environment" when conducting a risk evaluation.

EPA would be required to complete a risk evaluation on any chemical "as soon as reasonably possible, subject to the availability of resources," but not later than three years after its selection for evaluation. EPA must complete a risk evaluation requested by a manufacturer within two years. If EPA receives more requests for risk evaluations from manufacturers than it has resources to conduct by this deadline, however, EPA may delay initiating a manufacturer-requested risk evaluation until adequate resources are available, with the deadline to be adjusted accordingly. Moreover, if additional information is needed to make a risk evaluation determination, EPA may extend the deadline by up to 90 days after receiving the information, or two years after the deadline being extended, whichever is sooner.

HR 2576 provides that EPA cannot determine that a chemical substance will not present an unreasonable risk of injury to health or the environment if the agency determines that the substance under the intended conditions of use presents or will present an unreasonable risk of injury to one or more potentially exposed subpopulations.

A decision by EPA that a chemical substance will not present an unreasonable risk of injury to health or the environment will be considered a final agency action that is subject to judicial review.

HR 2576 requires EPA to "initiate" at least 10 risk evaluations in each fiscal year, "subject to the availability of appropriations."

Preemption of State Chemical Regulations

HR 2576 would prohibit any state or political subdivision from regulating a chemical substance if EPA has determined that the chemical does not present an unreasonable risk of injury under its intended conditions of use. If EPA issues a rule under TSCA Section 6 restricting a substance or mixture, a state or political subdivision cannot impose any additional restrictions on the substance or mixture, including any restrictions on articles containing the substance or mixture.

The prohibition would apply to both new and existing state chemical regulations. However, the bill does not preempt requirements imposed by states pursuant to a federal law or a state law pertaining to air or water quality or waste treatment or disposal (unless an action or determination by EPA "actually conflicts" with the requirement).

HR 2576 also does not preempt the authority of a state or political subdivision to continue to enforce "any action taken or requirement that has taken effect" (i) before August 1, 2015 under the authority of a state law "that prohibits or otherwise restricts the manufacturing, processing, distribution in commerce, use or disposal" of a chemical substance or (ii) pursuant to a state law that was in effect on August 31, 2003 (unless an action or determination by EPA "actually conflicts" with the action taken or the requirement). Additionally, the bill expressly does not preempt state tort and contract law and remedies.

PBT Chemicals

HR 2576 requires EPA to publish a list of chemicals that are considered to be persistent, bioaccumulative and toxic (PBT) within nine months after enactment of the bill. Within two years after enactment, EPA must designate any such PBT as a "chemical of concern" for which EPA can take regulatory action, if the PBT chemical has a likely exposure to the general population or a vulnerable subpopulation and scores "high" for either persistence or bioaccumulation and "high" or "moderate" for the other characteristic (persistence or bioaccumulation), pursuant to EPA's TSCA Work Plan Methods Document.

Confidential Business Information

HR 2576 would allow EPA to share confidential business information (CBI) with state, local and tribal government officials and healthcare professionals under certain conditions. The bill also would require CBI claims to be substantiated in writing. A CBI claim would expire after 10 years unless it is reasserted and requested to be renewed in writing before this time.

Order Authority to Require Testing

HR 2576 would give EPA the authority to require testing under TSCA Section 4 by administrative order for the purpose of conducting a risk evaluation. Under current TSCA, EPA can require the development of test data on chemical substances, but it can do so only through a formal rulemaking (if it makes certain findings) or a negotiated consent agreement.

Development of Procedures and Guidance

HR 2576 would require EPA to develop any procedures and guidance documents to carry out the bill within two years of its enactment. EPA also would have to review the procedures and guidance documents at least every five years thereafter.

Fees

HR 2576 removes the current dollar limits on the fees that may be charged under TSCA and gives EPA the authority to establish fees that are "sufficient and not more than reasonably necessary." The fees would be deposited into a TSCA Service Fee Fund, but the bill specifies that the fees will be "available for obligation only to the extent and in the amount provided in advance in appropriations Acts."

Report to Congress

HR 2576 requires EPA to submit a report to the House and the House E&C Committee within six months after the date of the bill's enactment (and at least every five years thereafter) estimating EPA's ability to conduct and publish risk evaluations and its plans to increase its capacity to do so; the resources necessary to conduct the minimum number of risk evaluations required by the bill; and the agency's capacity to promulgate any Section 6 rules that may be necessary.

Action by the US Senate

The US Senate Environment & Public Works Committee approved S.697, a bipartisan TSCA reform bill introduced by Senators Tom Udall (D-NM) and David Vitter (R-LA), on April 28, 2015, but the full Senate has not yet voted on the bill. HR 2576 is substantially different from the Senate bill, and if the Senate approves S.697, the differences between the two bills will have to be reconciled before any TSCA reform legislation becomes law.

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