TSCA Reform – Compromise Text

Existing Chemicals

Concern with Current Law. In the 40 years since TSCA was enacted there have been few EPA actions to regulate existing chemicals. Many blame the current law, including the requirement that EPA manage existing chemicals using the "least burdensome" regulatory option, as the reason for the lack of chemical regulation. Absent EPA action under TSCA, some states, litigants, and even consumer product retailers have been increasingly taking steps to restrict certain chemicals, not always relying on objective scientific analysis to make these decisions. Within the last year, both the House and Senate have passed bills to address the legal impediments to managing chemical risks under TSCA.

Compromise Approach. The House and Senate bills and the compromise text approach this problem similarly: by bifurcating the chemical regulation process into two steps (risk evaluation of a chemical and risk management of chemicals found to be problematic).

Risk Evaluation. The first step to deciding whether regulation of a chemical is warranted is a scientific evaluation of the risk posed by a chemical, looking at its hazards and exposures without considering cost or other non-risk factors. If that analysis indicates that a chemical's use presents an unreasonable risk, including to a vulnerable or susceptible population, then EPA will turn to the second step, a rulemaking to manage the risk.

Risk Management. Once EPA decides a chemical poses an unreasonable risk, the agency is required to issue a risk management rule, ranging from minimum labeling or notice requirements to an outright ban. In choosing regulatory options EPA must consider the effects of a chemical on health and the environment, the chemical's benefits, and economic consequences of the regulation including effects on the national economy, small business, and technology innovation. The considerations and the cost and benefits of the rule and cost effectiveness of the regulation must, to the extent practicable, also be factored in.

When deciding whether to ban or restrict a chemical, EPA must consider the availability of feasible alternatives. Unless they contribute significantly to the risk, replacement parts for certain complex durable and electronic goods that are designed prior to the risk management rule are exempt from a ban or restrictions. Articles may be restricted only to the extent necessary to address risk from exposure to that article. Critical uses of a chemical may be exempt from restriction if there is no safer alternative, the restriction would disrupt the economy, national security or critical infrastructure, or the chemical provides a substantial benefit to health, safety, or the environment.

New Chemicals

Concern with Current Law. Under TSCA section 5, 90 days before a new chemical goes on the market (or a significant new use is commercially introduced for an existing chemical) the manufacturer or processor must send EPA a notice and supporting information alerting EPA of its

intent to manufacture or process the chemical. If EPA takes no explicit action within those 90 days, commercial manufacturing may begin. The House-passed bill made no changes to TSCA section 5. The Senate-passed bill provides that EPA must review new chemicals and new uses, without regard to cost or other nonrisk factors, and affirmatively make an educated decision on the potential risk of the chemical – including regulation, before manufacturing begins.

Compromise Approach. The compromise text contains the key elements of the Senate-passed bill. EPA is required to review and make an affirmative finding about the level of risk posed by the new chemical without regard to cost. The chemical may not be commercially produced until EPA rules on it, and the chemical cannot be produced without being in compliance with EPA restrictions on the chemical that are without regard to cost. The compromise text attempts to tighten the timeline for EPA to take action requiring EPA to make a determination about, and choose a necessary regulatory option for, a chemical within 90 days, but no later than 180 days if more time is needed.

The compromise text gives EPA four determinations from which to choose regarding whether the new chemical or new use: (1) *presents* an unreasonable risk (in which case EPA must immediately take regulatory action under current law subsection (f)); (2) *may present* an unreasonable risk , is made in large quantities, or there isn't enough information to make a determination (which would trigger order requirements under subsection (e)); (3) is *likely not to present a risk* under the conditions of use (in which case manufacture may begin); or (4) is a subset of option #3, a *low hazard,* and manufacture may begin.

Chemical Testing

Concern with Current Law. TSCA Section 4 provides EPA sweeping authority to require testing of new and existing chemicals under a wide variety of circumstances so long as EPA has a reasonable basis for concern about the chemical. In order to require testing, EPA must also lack information that only new testing can address, the new testing must be mandated by rulemaking, and be subject to notice and comment. In the last 40 years, EPA has issued approximately 400 test rules due to the burden of issuing rules. The House-passed bill changed the testing section by giving EPA more deference with respect to the agency's authority for new testing. The Senate-passed bill replaced existing law by adding specific points in the chemical evaluation and regulatory process where EPA may require testing. The Senate bill also allows EPA to use order authority instead of being required to issue a rule. The Senate-passed version also contains language aimed at reducing animal testing.

Compromise Approach. The compromise text maintains existing law, but also specifies key points in the evaluation and regulatory process where EPA may order testing (e.g. prioritization for risk evaluation and the risk evaluation itself). In addition, the compromise text reduces animal testing required under TSCA.

Chemical Reporting

Concern with Current Law. TSCA Section 8 requires EPA to maintain an inventory of all chemicals that have ever been on the U.S. market. The House-passed bill did not amend this part of TSCA. The Senate-passed bill contained many details requiring EPA to update the inventory and it also required the use of certain chemical naming or nomenclature conventions.

Compromise Approach. The compromise text updates EPA's inventory and codifies industry nomenclature conventions.

Protection of trade secrets

Concern with Current Law. Existing TSCA Section 14 has stringent provisions for protection of confidential business information (CBI) that must be shared with EPA during the regulatory process. Once claimed, CBI remains protected until EPA finds it does not meet legal requirements for

protection. Some groups claim that these stringent protections allow industry to hide information about chemicals from the public. While the House-passed bill maintained the essence of existing law and clarified that trade secrets were protectable within health and safety studies, it also limited duration of protection to 10 years and allowed more categories of people to obtain trade secret information to protect health or the environment. The Senate-passed bill created a system to claim, substantiate and re-substantiate, review, adjudicate claims, and mandatorily disclose trade secrets.

Compromise Approach. The compromise text specifies that EPA must continue protecting trade secrets submitted to it for 10 years, including when disclosure of proprietary chemical formulas would reveal secrets about the chemical manufacturing process. The compromise text adopts the Senate's system to claim, substantiate and re-substantiate, review, and adjudicate claims for protection of trade secrets.

State-Federal Relationship

Concern with Current Law. There is little concern with existing law because EPA has regulated so little. The concern would be that if EPA became more active, federal preemption would nullify existing state and local laws – including judicial rulings – and give preemption to certain new chemicals uses. The House bill generally maintains the preemption provisions of existing TSCA, but inserted language that: prevents state and local laws from conflicting with federal requirements; saves certain types of state laws form preemption – including California's Proposition 65 and Green Chemistry laws; and protects state tort and contract laws. The Senate bill instituted a preemption "pause"(a time period during which states are not allowed to enact or enforce certain statutes and regulations); permitted several exemptions to preemption; ensured state court decision for criminal, tort, and contract cases were not preempted; and maintained California labeling and chemical control laws.

Compromise Approach. Preemption under the compromise text begins with a general rule (subject to later provisions saving certain state laws) that states and local governments may not (1) duplicate federal information developments requirements, (2) restrict a chemical that EPA's scientific risk evaluation found does not present an unreasonable risk, EPA has published risk management regulation; or required notification for a significant new use or a new chemical. Preemption begins when the administrator defines the scope of a risk evaluation and ends either 30 months after that or when a risk evaluation is completed, whichever is earlier. This provision does not restrict state authority to continue enforcing a law enacted prior to the risk evaluation scoping, but this does not allow a state to enforce a new restriction established after the risk evaluation scoping. Federal preemption applies only to the scope of the risk evaluation or to the significant new uses under section 5.

There are exceptions to the general preemption rule. These include state laws carrying out federal laws, reporting requirements that are not otherwise required under federal law, or related to water or air quality, or waste treatment or disposal. Also state laws restricting chemicals that were enacted prior to April 22, 2016, are not preempted, nor are any actions taken by a state pursuant to a law enacted prior to September 2003.

EPA may waive preemption if EPA determines that compelling conditions warrant it, the state law is scientifically based, and the state law would not unduly burden interstate commerce. EPA may also waive the preemption pause if, no later than 18 months after EPA has initiated the prioritization process for a chemical substance or 6 months after scoping the risk evaluation, whichever is sooner, a state has acted to restrict the chemical. Common law rights of action, and laws for civil relief, including those for civil damage or penalties for criminal conduct are saved from preemption.

Finally, the preemptive effect under TSCA prior to enactment of this bill will govern actions taken by EPA prior to enactment of the new bill as well as on chemicals subject to EPA section 6 action.

Science

Concern with Current Law. Concerns have been raised by the National Academy of Sciences about how EPA has been doing risk assessments on chemicals. Since regulation is predicated purely on a review of risks, the concern is that EPA not make determinations that are inconsistent with the best available, objective, and high quality scientific practices.

Compromise Approach. The compromise text (like both the House and Senate-passed bills) requires that science-based decisions be made based upon the weight of the scientific evidence. The compromise text (like the Senate-passed bill) requires that EPA use scientific information, technical procedures, measures, methods, and protocols predicated on the high quality science elements of the House-passed bill.

Fees

Concern with Current Law. TSCA section 26 provides that EPA can only collect fees for information collected pursuant to testing rules in section 4 and new chemicals and new uses in section 5. The fees, based on 1976 costs, are capped at $2,500 and small businesses were required to pay no more than $100. In light of the major new requirements imposed by the underlying text, increased fees are necessary to offset the resultant costs. The House-passed bill maintained existing user fees with two exceptions: the House bill lifted the caps based on 1976 costs and added user fees in cases when a manufacturer initiates a risk evaluation on an existing chemical. The Senate-passed bill also removed the statutory caps on fees and included fees for other steps in the regulatory process, including submitting reporting data. The Senate version would allow fees collected under one provision to be used to fund activities in other provisions, but capped most total fee collection at 25% of EPA's TSCA chemical regulation budget or $25 million, whichever is lower.

Compromise Approach. The compromise text allows fees collected under one provision to be used to work on the same chemical under testing, evaluation and regulation, and information protection provisions. The bill caps overall fee collection (with some exceptions) to 25% of EPAs cost for regulating new and existing chemicals and test orders or $25 million, whichever is lower, and requires manufacturers who request risk evaluations of their chemicals to pay the full cost of the evaluation and regulation.

Other Provisions

Amendments to the Mercury Export Ban Act of 2008 *clarifying waste management obligations of the U.S. government and of elemental mercury producers.*

*"**Trevor's Law"** to designate and investigate cancer clusters.*

S. 1916 (H.R. 4111), the Rural Health Care Connectivity Act of 2016, authored by Senator John Thune (R-SD). This section adds "skilled nursing facilities" to the definition of a Health Provider in Section 254 of the Communications Act related to Universal Service. The section defines skilled nursing facility by cross-reference to the definition used in the Social Security Act. The section requires the changes identified in the bill be made six months after the legislation is enacted.

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