An Abbreviated Guide to the Frank R. Lautenberg Chemical Safety for the 21st Century Act

Summary: The reform of the Toxic Substances Control Act (TSCA) gives EPA important new authorities to tackle the problem of toxic chemicals. For the first time, there are also enforceable deadlines and schedules for EPA work on chemicals as well as dedicated funding from fees paid by industry. The pace of change will be slow, however. There are some unnecessary activities required that will divert resources and there are some loopholes in the law. State authority is unduly infringed under the bill, but enough is preserved that states can still take the lead in public health interventions for many if not most, chemicals.

Highlights of the Act

Safety Standard: The most important reforms in the law are in Section 6, which governs chemicals that are already on the market. The bill addresses the limitations on EPA authority that prevented it from regulating asbestos (and by implication, other chemicals) after a 1991 court decision. Under the bill, EPA must now decide whether to regulate a chemical based solely on health and environmental factors. It must identify populations that are disproportionately at risk either due to greater exposure to the chemical or greater susceptibility to injury from the chemical. The decision to regulate or not is keyed off of the risk to these groups and any restrictions must protect these groups. Taken together, these reforms should lead to chemical restrictions that are meaningful, not just to the general public, but especially to populations in heavily impacted communities and to pregnant women and children.

Analytical Burden: The new law also removes the requirement in current law that EPA must choose the "least burdensome" way of addressing the risk posed by a chemical. This seemingly innocuous phrase was a major factor in EPA's inability to regulate asbestos, partly because of the way it was interpreted by the court. The court effectively found that EPA had to prove it had analyzed every conceivable way of restricting asbestos and had chosen the one that was "least burdensome" to industry. Under the new law, EPA must conduct both a cost-benefit and a cost-effectiveness analysis of any proposed restrictions and describe their impact on the economy. However, the bill makes clear that those analyses are to guide EPA in choosing among a limited number of regulatory options that each ensure the chemical is safe for the identified populations. The analytical burden on the agency is still potentially significant, therefore, but EPA is still required to apply the needed public health and environmental protections.

Deadlines: The mechanism for EPA to choose a chemical to review is to propose it as a

High Priority chemical. Within 12 months of proposal the EPA must finalize the prioritization or change its mind citing new information. Once prioritization is finalized, the EPA must conclude the safety review (called a “risk evaluation”) within 3 years. If it needs more information or time for analysis it can extend the deadline an additional year. If the chemical flunks the safety review, the EPA then has 2 years to finalize a rule specifying the restrictions it will place on the chemical in order to protect public health. It can get an extension of up to one year, if needed, to formulate the restrictions. The public can sue the agency for failure to meet these deadlines, which is what makes them “enforceable.” The deadlines are obviously generous, but they are also deadlines. With adequate resources and political will EPA could move faster.

Schedule: The law also establishes a minimum enforceable schedule. It requires EPA to identify a minimum of 10 chemicals as High Priority within 180 days of enactment and another 10 within 3.5 years of enactment. At that point EPA is required to have a minimum of 20 chemicals under review at all times until every chemical in commerce has been prioritized as either High or Low. There is a mechanism whereby chemical manufacturers can nominate a chemical for EPA to review, and EPA must oblige, as long as the manufacturer pays for the costs. The number of manufacturer-requested evaluations cannot exceed the number of EPA-initiated evaluations at any given time. As with the deadlines, this schedule is clearly meager, but it is also a minimum. With adequate resources and political will EPA could tackle a greater number of chemicals.

Persistent, Bioaccumulative, and Toxic Chemicals (PBTs): The law expedites action on some of these chemicals, which are widely considered to pose great risks to public health and the environment. The EPA has already identified 30 PBTs through its Workplan program. The law requires the agency to apply a potency and exposure criteria to that group and subject any chemicals that meet the criteria to an expedited process whereby they must be restricted within three years and exposure reduced more aggressively than with other chemicals. However, manufacturers can use some of the allotted manufacturer requests (from the process above) to force EPA to first conduct an evaluation of the PBT if the manufacturer is willing to pay for it. Depending on how broadly EPA interprets the PBT criteria and whether manufacturers use their request chits on these chemicals, the provision could lead to expedited action for a significant group of known toxic chemicals.

State Authority: All state restrictions on chemicals that have been taken as of April 22nd of this year are allowed to remain in place regardless of what EPA decides about the same chemical in the future. (A provision known as “grandfathering.”) States are free to initiate new restrictions on a chemical until and unless EPA names the chemical as High Priority and publishes a document outlining the “scope” – the uses, conditions, health concerns, etc. ¬– of the risk evaluation they plan to undertake. States are then prohibited (“preempted”) from establishing new restrictions that address the same scope. If EPA declares the chemical safe for all of those uses and conditions, the preemption becomes permanent. If EPA declares any of the uses and conditions in the scoping document unsafe, the preemption is lifted and states are free to impose new restrictions while EPA takes two to three years to decide on its own restrictions. Once EPA establishes its restrictions, the preemption kicks in again and becomes permanent unless a state obtains a waiver that requires it to meet several criteria.

Certain categories of state chemical regulation are exempt from preemption altogether.

These include restrictions pursued under state laws that relate to air, water, or waste or which derive from delegated authority under another federal law (like OSHA.) State information collection and reporting requirements are exempt as are any actions taken under a state law passed before 2003. This last provision was designed to protect California's Proposition 65 but it applies to any other pre-2003 law. The temporary preemption provision does not apply to the first 10 chemicals that EPA names or to industry-requested evaluations of any EPA Workplan chemical. This last provision was included to ensure that several recent and pending state actions on Workplan chemicals can take effect.

As this description shows, the preemption provisions in the bill are complicated and over-reaching. However, because of the exemptions described and the fact that preemption is tied to the schedule of EPA reviews, there remains ample room for continued state leadership.

Testing Authority: Under current law, EPA must undertake a formal rulemaking – a significant legal administrative process that requires years – in order to require a chemical manufacturer to conduct toxicity testing. As a result, only a fraction of chemicals have significant health and safety information. The new law allows EPA to require toxicity testing through the vastly simpler mechanism of an administrative order. EPA is required to deploy a "tiered testing" approach – whereby a chemical must first raise a red flag in a screening level test before more extensive tests are required. The law expressly provides however, that EPA can move straight to the more extensive testing if it believes it is necessary. The overwhelming scientific consensus is that whole animal testing (including on zebra fish) is still required to accurately assess whether a chemical causes many of the known "toxicities" of concern. Animal testing provisions in the new law, while appropriately encouraging the use of non-animal methods where available, also go beyond that in ways that, depending on interpretation, could discourage independent research that is needed to identify and intercept chemicals that could harm human and animal populations.

In general, the improvements to testing authority in the bill outweigh the limitations and create the potential for substantial improvements in our understanding of toxic chemicals. There is nothing in the bill that requires EPA to use the new authority however, so the extent that it does will likely be driven by external demand for more information about chemicals.

Confidential Business Information: Under current law, much of the limited information that is available about chemicals has been hidden from the public because of overly broad and often-abused provisions allowing manufacturers to claim information as confidential. Under the new law, EPA can share information with state and local governments, first responders, health providers and researchers as long as the confidentiality is maintained. New guidelines are created to provide greater clarity about what information can and cannot be claimed as confidential. Confidentiality claims relating to the very identity of a chemical (its actual, technical name) have been among the most controversial in current law. The new law requires that manufacturers substantiate the basis for claiming chemical identity as confidential and creates a deadline for EPA review of CBI claims. At the same time, it clarifies EPA's ability to protect chemical identity, when it would otherwise be revealed as part of a health and safety study and may require broader CBI protection than under current law. Overall, the new law should result in more rigorous

and expeditious scrutiny of CBI claims by EPA, but could result in enhanced withholding of chemical identity as part of a health and safety study.

Imported Products: Existing law has a mechanism whereby the EPA can require manufacturers or importers of products (called "articles" in the law) to notify the agency if the product contains a chemical of concern. (The mechanism is called a Significant New Use Rule.) The purpose of the mechanism is to ensure that new uses of a chemical – which may not have been regulated because they were not anticipated – don't proliferate to such a degree that they cause harm. Several companies successfully lobbied for a provision in the new law that makes it harder for EPA to require this notification in the future. Under the new law, EPA must make "an affirmative finding" that the article presents a "reasonable potential for exposure" before it can require notification.

Prioritization: The legislation's criteria and process for naming a chemical as High Priority are overly complicated and may divert agency time and energy away from the pressing business of evaluating the safety of the chemical. Also the agency is required to undertake a rulemaking in the first year to develop a new prioritization policy. (The current policy is what led to the Workplan chemical list.) The rulemaking inherently requires agency staff resources and precious time. The new legislation also contains a provision for EPA to name at least 10 chemicals as Low Priority, and empowers the agency to add more. Under the bill, the agency must have sufficient information to determine that a chemical is "likely not to present an unreasonable risk." The Low Priority designations can be challenged in court. The criteria and process should prevent the agency from falsely exonerating chemicals, but because Low Priority chemicals are not subject to full evaluation or restrictions, there may be pressure from some in regulated industry to achieve the designation even where it is not warranted.

New Chemicals: Current law requires a manufacturer to submit a "pre-manufacture" notice to EPA before it can commence production of a new chemical. No minimum health and safety data is required. EPA has 90 days to review the chemical. If it takes no action, the manufacturer can commence production. However, it has the ability during this period require testing before a chemical can proceed or to place a Significant New Use Rule on the chemical as a condition of allowing it on the market. (It can require the manufacturer to report if the production volume or uses of the chemical change from what the manufacturer submitted.) With this authority EPA routinely blocks or restricts new chemicals every year, but it also allows most to move forward to production. The new law requires EPA to make an affirmative finding that the chemical is likely not to present an unreasonable risk before it can commence production. Though minimum information is still not required, the provision should strengthen the oversight of new chemicals.

SOURCE: http://saferchemicals.org/get-the-facts/an-abbreviated-guide-to-the-frank-r-lautenberg-act-chemical-safety-in-the-21st-century-act/