How would TSCA reform legislation address key flaws in TSCA?

This is an update of a series of five posts to the <u>EDFHealth blog</u> that examine key flaws in the Toxic Substances Control Act (TSCA) and how recent bipartisan reform proposals would address them. While less talked-about than the contentious issue of preemption of state authority, these elements are critically important to achieving meaningful reform of TSCA.

The series has been updated to reflect the latest versions of the Senate and House TSCA reform legislation:

- The *Lautenberg Act*, <u>S. 697</u>, is the bipartisan TSCA reform legislation introduced in the Senate in March and passed in revised form out of the Environment and Public Works Committee in April.
- The *TSCA Modernization Act* of 2015, <u>H.R. 2576</u>, is the bipartisan legislation introduced in the House in May and passed by the full House in June.

The five posts address the following elements of TSCA reform:

- Enhancing testing authority
- EPA review of new chemicals
- How chemicals are selected for safety evaluations
- Confidential business information
- Consideration of costs and other non-risk factors

Each post first discusses the relevant flaws in TSCA, and then the extent to which the Senate and House legislation addresses those flaws.

Enhancing EPA testing authority (back to top)

This post deals with EPA's authority to require companies to conduct testing of their chemicals.

Under *current TSCA*, for chemicals already on the market, EPA must generally go through notice-and-comment rulemaking (which is usually a multiyear process) before it can require testing. EPA must also first make certain risk or exposure findings in order to require testing, namely that a chemical:

- may present an unreasonable risk; or
- is produced in substantial quantities and either enters the environment in substantial quantities or there is or may be significant/substantial human exposure.

The first of these requirements is a *Catch-22*: showing potential risk is not an easy task without the data that required testing would provide. The second requirement is also circular in nature. For example, a highly potent carcinogen could be harmful at much lower exposures than a weak one. The hazard information that testing would provide could help EPA determine what actually are substantial or significant levels of production, release or exposure of a given chemical. Yet this statutory requirement has forced EPA to use one-size-fits-all thresholds to define "substantial" and "significant." EPA has defined "production in substantial quantities" to be 100,000 or more kilograms per year (for new chemicals) or one million or more pounds per year (for existing chemicals). That level all but precludes EPA from requiring testing of lower-volume chemicals that could still be toxic enough to pose significant risk.

As a result of these constraints, EPA has managed to require testing on fewer than 300 of the 62,000 chemicals that were on the market and grandfathered in when TSCA was first enacted.

EPA fares a little better with respect to new chemicals, where it can use consent orders to require testing. EPA staff estimate the agency imposes some type of testing requirement on about 4% of the Premanufacture Notices (PMNs) it reviews. With EPA having reviewed nearly 40,000 PMNs over the course of TSCA, that's about 1,600 new chemicals for which any testing was required.

Let's generously assume all of those chemicals went on to enter commerce (a clear overestimate, as only about half of PMN'd chemicals go on to enter commerce). This would mean that on the order of 2,000 of the 85,000 chemicals -2.4% — on the TSCA Inventory have had some testing required under TSCA. Put another way, EPA has not required any testing of 97.6% of the chemicals that have been on the market at some point since TSCA passed in 1976.

How would TSCA reform legislation address this problem?

The Lautenberg Act allows EPA simply to issue orders to require testing instead of going through rulemaking (though it must justify why it is using an order rather than a rule). It also strikes the requirement that EPA first show potential risk or high release or exposure in order to require testing. EPA can require testing to inform all actions it must take, including new chemical reviews, prioritization, safety assessments/determinations and development of risk management rules. The bill generally requires EPA first to request submission of the needed information before mandating testing; and EPA cannot require testing as a means to establish minimum information sets for chemicals generally.

So, while the bill does not provide EPA with unfettered authority to require testing, it provides a major expansion in such authority, a clear improvement over current TSCA.

The **TSCA Modernization Act** also allows EPA to require testing via issuing an order rather than through a rulemaking, and does not include a requirement that EPA justify why it is using an order rather than a rule. Except for testing necessary to conduct a risk evaluation, however,

the bill retains TSCA's current *Catch-22* requirement that, before it can require testing, EPA must first show potential risk or high release or exposure.

EPA review of new chemicals (back to top)

This post deals with EPA authority to review new chemicals prior to their entry into commerce.

TSCA divided the universe of chemicals into two groups: "Existing chemicals" are those on the market at the time the first TSCA Inventory was established (1979), numbering some 62,000 chemicals. These chemicals were grandfathered in by the original law, with no mandate for them to be tested or reviewed for safety. "New chemicals" are those that entered commerce at some point since 1979, numbering some 23,000 chemicals. Between 500 and 1,000 new chemicals enter commerce in a typical year. (Given these large numbers, it's surprising how relatively little focus there has been on the way bipartisan reform proposals would address new chemicals. I'll amplify on this point at the end of this post.)

Section 5 of TSCA provided EPA with authority to review new chemicals prior to market entry. However, it imposed substantial constraints on EPA in conducting those reviews. Under TSCA, a company is generally free to start making and selling a new chemical at the end of a 90-day review period, unless EPA finds the chemical "may present an unreasonable risk." That is, no affirmative safety decision is required, and the burden is on EPA to find a concern even when safety data are wholly lacking.

I have blogged extensively about the limitations of EPA's new chemicals reviews. Let me briefly summarize the key problems here, and refer readers to these blog posts for more detail.

- **No data, no problem**: No up-front testing requirement or minimum data set applies to new chemicals.
- *Guessing game*: EPA is forced to heavily rely on limited models and methods to predict the toxicity or behavior of a new chemical.
- *Catch-22*: While EPA can require testing of a new chemical on a case-by-case basis, it must first show the chemical may pose a risk not an easy task without any data in the first place!
- *One bite at the apple*: EPA typically gets only a single opportunity to review a new chemical.
- *Crystal-ball gazing*: EPA has to try to anticipate a new chemical's for-all-time future production and use.
- **Black box**: New chemical reviews lack transparency.
- **Anti-precaution**: In deciding whether to require testing or controls for a new chemical, EPA effectively equates lack of evidence of harm with evidence of no harm.

How would TSCA reform legislation address these problems?

The Lautenberg Act mandates for the first time that EPA make an affirmative finding of safety for each new chemical as a condition for market access. It makes clear that manufacture of a new chemical can only start if EPA determines it is likely to meet the safety standard. Where EPA determines the chemical is *not* likely to meet the safety standard, it must preclude manufacture or impose restrictions sufficient for EPA then to find the chemical is likely to meet the safety standard.

If EPA finds it has insufficient information to make a determination, it can suspend the review pending receipt of the information, or impose restrictions sufficient for it to make the likely-safe determination even in the absence of the information. While the bill does not require up-front safety data sets for new chemicals, as noted in my first post in this series, EPA can require testing of new chemicals as needed. It can do so by issuing orders as well as through negotiating consent agreements. And it need not first show potential risk or high release or exposure in order to require testing.

Once a new chemical enters commerce, it becomes subject to the bill's prioritization process. EPA can review the chemical at any time based on new information that it develops or obtains after the chemical is on the market. The bill also requires EPA to make public all documents relating to new chemicals and EPA reviews, subject to the bill's confidential business information (CBI) protections.

The new chemicals provisions of the Lautenberg Act go far to address the fundamental problems with TSCA's Section 5.

The **TSCA Modernization Act** makes no changes at all to section 5 of TSCA, leaving in place all of the constraints EPA faces under current law.

One final note: It is interesting how much of the debate over TSCA reform legislation has focused on provisions that would affect far smaller numbers of chemicals than those that pass through EPA's New Chemicals Program every year. Major contention has surrounded the number of existing chemicals EPA should be reviewing (with even the most ambitious proposal setting that number at 75 chemicals over a several-year period). Similarly, there has been much debate over the limited number of high-priority chemicals that states might want to, but under S. 697 could not, regulate during the period between when EPA takes up such a chemical and when it takes final action. While those questions are important, far less attention has been paid to how EPA's reviews of new chemicals would be affected by the various TSCA reform proposals; *yet, many hundreds of new chemicals undergo such reviews year in and year out*. As this post makes clear, the reform proposals differ starkly with respect to how new chemicals would be reviewed prior to market entry.

How chemicals are selected for safety evaluations (back to top)

This post deals with how EPA would select which chemicals would undergo safety evaluations.

Under *current TSCA*, EPA has no mandate to review the safety of existing chemicals. There are no pacing requirements, such as specifying minimum numbers of chemicals to be examined. The law provides no criteria for EPA to use in identifying chemicals that may pose risks. There are no requirements for EPA to establish goals for reviews or schedules for any reviews it does undertake.

Safety reviews are rarely undertaken, and often consume many years (or even decades) – in large part because there are no mandates or deadlines. As a result of these aspects of the current law, only about 2% of the chemicals that were on the market at the time TSCA was enacted have undergone any sort of safety review.

In 2012, EPA on its own initiative undertook a prioritization process that has led to identification of about 90 so-called "work plan" chemicals, for which EPA is conducting or intends to conduct risk assessments; five have been completed to date.

How would TSCA reform legislation identify chemicals to be subject to safety reviews?

The Lautenberg Act establishes a risk-based prioritization process through which EPA would identify chemicals to be subject to safety assessments and safety determinations. EPA is mandated to prioritize *all* chemicals in active commerce. Specific findings and criteria to be used to identify low- and high-priority chemicals are described in the bill, with details to be developed through notice-and-comment rulemaking. Persistence and bioaccumulation are listed as explicit factors EPA is to consider in prioritizing chemicals.

EPA is to conduct safety assessments and safety determinations for all high-priority chemicals, and to set schedules for doing so. The bill specifies concrete judicially enforceable deadlines for each major step: prioritization, safety assessments and determinations, and promulgation of regulations for chemicals found not to meet the bill's safety standard.

Under the bill, EPA can designate any of its current "work plan chemicals" as high-priority, and at least half of all high-priority chemicals EPA identifies are to be drawn from the work plan list until all such chemicals have been so designated. Preference is to be given to work plan chemicals that rank high on persistence and bioaccumulation. EPA can continue or initiate assessments on any of these work plan chemicals while the bill's new prioritization and assessment procedures are put in place.

With respect to pace, EPA must include at least 10 chemicals on the initial high-priority list (as well as at least 10 on the low-priority list, which are chemicals EPA finds are "likely to meet the

safety standard"). By three years after enactment, at least 20 high-priority and 20-low-priority chemicals must be listed. By five years after enactment, at least 25 high-priority and 25-low-priority chemicals must be listed.

More generally, EPA is to prioritize chemicals at a pace commensurate with available resources, publish an annual goal for the number of chemicals to be prioritized, and subject all chemicals to prioritization in a "timely manner." An annual plan and schedule for the completion of safety assessments and determinations must be made public. As final action is taken on a high-priority chemical, at least one new substance must replace it on the high-priority list.

In addition to chemicals that EPA designates as high-priority, the bill provides for companies to request that EPA assess a chemical it has not so designated, and at its discretion EPA can grant such requests. The number of such requests granted is to constitute no less than 25% and no more than 30% of the cumulative number of high-priority chemicals subject to safety assessments and determinations. EPA cannot give these industry-requested assessments preference over those it conducts on high-priority chemicals. Companies are to pay fees to cover the full costs of these assessments. Unlike high-priority chemicals, initiation of assessments on these company-requested chemicals does not trigger preemption of new state requirements.

Industry can also nominate chemicals already on EPA's work plan for assessments; EPA has discretion to designate such requested chemicals high-priority and if it does, industry is to pay fees to cover 50% of EPA's assessment costs. The 25% minimum and 30% cap noted above do not apply to these chemicals, and their designation as high-priority is preemptive of new state actions during the safety assessment and determination phase.

The *TSCA Modernization Act* does not include a prioritization process, nor does it contain any mandate for EPA to review all existing chemicals, which would largely perpetuate the situation created under the original law whereby thousands of chemicals can stay in commerce without any review.

As with current TSCA, EPA would have authority to review existing chemicals; and the bill calls on EPA to conduct a "risk evaluation" for any chemical it determines "may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use." Chemicals on EPA's work plan may be subjected to a risk evaluation without having to make the "may present" finding just noted.

Finally, the bill directs EPA to initiate 10 or more risk evaluations each fiscal year — but "subject to the availability of appropriations." Beyond this provision, the bill does not address the pace, number of chemicals, or timelines for identifying chemicals to undergo risk evaluations, nor does it set goals to guide or direct EPA in undertaking risk evaluations of existing chemicals. EPA could not levy fees for any risk evaluations it initiates, including those for work plan chemicals.

Under the bill, EPA would be *required* to conduct a risk evaluation of any chemical that any manufacturer requests it conduct. The full costs of such risk evaluations would be borne by the manufacturer. In contrast to the provision for industry-requested assessments in the Lautenberg Act described above, this process under the House bill is unbounded: No limit is set on the number of such requests, all of which EPA would have to grant. Such risk evaluations would have to be completed within 2 years, in contrast to the 3-year deadline for EPA-initiated risk evaluations. Only if EPA could not meet the 2-year deadlines for industry-identified chemicals could it limit the number of those risk evaluations it undertakes.

These mandates mean that EPA could well spend virtually all of its effort evaluating those chemicals industry requested it evaluate (which could be sought for non-risk-related reasons, ranging from seeking a competitive advantage to seeking permanent relief from state regulation), rather than those EPA would identify as posing the greatest potential risk.

The bill requires EPA to identify chemicals that are persistent, bioaccumulative and toxic (PBT) — but *excluding all metals and metal compounds* — to which exposure is likely. These are to be listed within 2 years and subject to risk management "to reduce likely exposure to the extent practicable" within 2 more years. However, if EPA finds such a chemical "may present an unreasonable risk" and initiates a risk evaluation, or if any company requests EPA conduct a risk evaluation of such a chemical, the requirement to subject the chemical directly to risk management does not apply.

Confidential business information (back to top)

This post deals with how EPA would address industry claims for protection of confidential business information (CBI) pertaining to chemicals, and disclosure of CBI to various parties. The discussion is divided into three parts, addressing: (1) CBI claims for chemical identity, (2) access to health and safety information and (3) duration of CBI claims.

CBI claims for chemical identity

Under *current TSCA*, companies can claim the identities of any of their chemicals to be CBI. As a result, the identities of about 17,000 chemicals (out of the 85,000) on the TSCA Inventory are hidden from public view, having been claimed by their makers to be CBI. EPA can challenge such CBI claims on a case-by-case basis, but it has no mandate to review them and rarely mounts challenges because of the resources required.

Why is knowing the identities of chemicals in use important? When a chemical's identity is hidden, that means people — consumers, researchers, health professionals, etc. — cannot determine whether that chemical is present in products, the environment or even in our bodies, nor can they link it to other information about potential health effects or exposures.

The Lautenberg Act limits any presumption of protection from disclosure of chemical identities to the period before they enter the market; and any such claim for a chemical after market entry has to be substantiated and reviewed by EPA.

Importantly, EPA is also required to review and require substantiation of past chemical identity claims for all active chemicals now on the confidential portion of the TSCA Inventory. This review must be completed within five years of enactment. EPA must also review any CBI claim for the identity of any inactive chemical at the time it is moved to active status. Chemical identities not already on the confidential portion of the inventory or added to it per prescribed procedures cannot be claimed confidential in any context.

The *TSCA Modernization Act* makes no changes to current TSCA for chemical identity claims that were made before enactment. That means it would continue the status quo under which those claims are not required to be reviewed by EPA, nor subject to a requirement for companies to re-justify whether the chemical identities are still legitimate trade secrets, sometimes long after the chemicals first entered the market. Such claims made after enactment would be required to be justified by the claimant, but, as under current TSCA, no EPA review of such claims would be mandated.

Access to health and safety information

Under *current TSCA*, companies are free to claim virtually any information they submit to EPA is CBI. EPA cannot disclose information claimed CBI to the public, to state and local agencies, to health providers or even to first responders. Health and safety studies and their underlying data are generally not eligible for CBI protection under TSCA, but, until recently EPA routinely allowed those studies, or the identities of the studied chemicals, to be hidden from public view.

The Lautenberg Act retains current TSCA's exclusion of health and safety studies and their underlying data from being claimed CBI. For claims going forward relating to other types of information (e.g., the uses of the chemical or the identity of the company making it), they can only be protected from disclosure if they are legitimate trade secrets, and generally must be substantiated at the time they are asserted. EPA is required to review a representative subset, including at least 25 percent, of all such claims.

For the first time, state and local governments as well as health professionals would have access to CBI, per agreements made with EPA that they keep the information confidential.

EPA would have authority, at any time, to review and require resubstantiation of any claim — whether asserted in the past or future — for chemicals EPA designates as high-priority, finds have sufficient information for a safety determination, or are inactive. EPA also could review and require resubstantiation of claims for information the disclosure of which would assist EPA

in conducting safety assessments, making safety determinations, or developing risk management rules.

EPA is mandated to review a CBI claim and require resubstantiation if necessary to comply with a FOIA request; if EPA has reason to believe the claim is not valid; or for chemicals found not to meet the safety standard. CBI claims for a chemical that EPA bans or phases out would generally expire.

All CBI claims relating to chemicals being banned or phased out would be subject to a rebuttable presumption that the information should be disclosed to the public; EPA's intent to disclose would be subject to appropriate notification of the submitter of the CBI and an opportunity to rebut the presumption that the public interest in disclosure outweighs the private interest in protection of the information. EPA's decision is to be based on the objective of maximizing disclosure of information relevant to protecting health and the environment.

The **TSCA Modernization Act** requires CBI claims made after enactment to be justified by the claimant, but as in current law, no EPA review of such claims would be mandated. EPA has authority – but not a mandate – to provide State and local governments with access to CBI. EPA must provide health professionals (though not first responders) with access to CBI, per agreement that they keep the information confidential.

The bill would significantly expand current TSCA's exceptions from disclosure for information relating to chemical identities in the context of health and safety information. Under *current TSCA*, two exceptions to the general allowance for disclosing health and safety information are provided: (1) data which discloses processes used in the manufacturing or processing of a chemical substance or mixture, or, (2) 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 bill adds a third exception: (3) "data that disclose formulas (including molecular structures) of a chemical substance or mixture." The inclusion of the term "molecular structures" in this addition goes beyond information relating to a chemical formulation (the extent of the revision made to this provision in the first discussion draft of the House bill), and would expressly preclude EPA from identifying a chemical that is the subject of health and safety information it is making public, if that chemical identity were claimed CBI. This would have the effect of reversing EPA's policy and practice under current TSCA.

Duration of CBI claims

Under *current TSCA*, CBI claims are not subject to time limits and remain in place until and unless challenged by EPA. That means information subject to claims made many years or even decades earlier remains hidden from public view, even though the original basis for the claim may have long since changed.

Under *the Lautenberg Act*, except for claims for information deemed always eligible for protection (e.g., customer lists, detailed process information), CBI claims expire after 10 years unless resubstantiated. Claims made before enactment that EPA reviews (including the past chemical identity claims discussed above) would also be subject to the 10-year, renewable, limit. In both cases, EPA is required to review all requests for renewals of claims pertaining to chemical identity, and a representative subset (including at least 25%) of all other renewal requests.

The **TSCA Modernization Act** subjects all claims made after enactment to a 10-year time limit, which can be extended by filing a renewal request. EPA review of any such requests is not required. Past CBI claims would not be subject to any time limit and hence would remain in place indefinitely unless challenged by EPA.

Consideration of costs and other non-risk factors (back to top)

This post deals with how costs and other non-risk considerations factor into safety and regulatory risk management decisions.

The safety standard

Under *current TSCA*, EPA's determination of whether or not a chemical presents an "unreasonable risk" requires the agency to formally balance consideration of costs and other non-risk factors against the potential danger to human health or the environment.

The Lautenberg Act retains the term "unreasonable risk" as its safety standard but, in defining the standard, explicitly precludes EPA from considering costs and other non-risk factors in making safety determinations. This same exclusion of costs and other non-risk factors is made in each relevant provision throughout TSCA where the term "unreasonable risk" is used, to make clear that EPA's decisions as to the safety of chemicals are based solely on considerations of risks to human health and the environment.

The TSCA Modernization Act also retains the term "unreasonable risk" as its safety standard, but does not define the safety standard. The bill specifies that, in conducting a risk evaluation, EPA "shall not include information on cost and other factors not directly related to health or the environment;" and that "[t]he Administrator shall not consider costs or other non-risk factors when deciding whether to initiate a rulemaking under subsection (a)." The bill does not explicitly state, however, whether the determination of "unreasonable risk" is to be based solely on risks to human health or the environment. The qualification regarding costs and other non-risk factors is not included in other TSCA provisions that invoke unreasonable risk, such as those applicable to new chemicals and testing, leaving open the prospect that costs could or would have to be considered in those contexts.

The House bill includes the requirement that EPA show a chemical "may present an unreasonable risk" in order to initiate a risk evaluation of the chemical. While the language has been qualified to indicate the finding can be made "because of potential hazard and a potential route of exposure under the intended conditions of use," the language still requires EPA to make a risk finding in advance of and as a condition for initiating a risk evaluation, a potential *Catch-22*.

Regulatory requirements

Under *current TSCA*, EPA is required to conduct a formal analysis of costs and benefits of any proposed restriction of a chemical, and to show that the benefits of the restriction outweigh its costs. It also must demonstrate that any restrictions it chooses to impose are the "least burdensome" among those able to address the identified risks, a showing that in practice has proven excessively onerous. These requirements have proven to be fatal flaws in TSCA, imposing evidentiary and analytic burdens on EPA so severe that it could not meet them even for the deadly human carcinogen asbestos.

The Lautenberg Act strikes the "least burdensome" language and clarifies that a balancing test for costs and benefits is not required. It goes further to make clear that cost considerations cannot override the requirement that restrictions be sufficient to ensure chemical safety: Where a chemical does not meet the safety standard, EPA "shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard."

In deciding what restrictions to impose on a chemical found not to meet the safety standard, EPA is to consider "to the extent practicable based on reasonably available information, quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator." As part of its analysis, EPA is also to review any technically and economically feasible alternatives to the chemical EPA deems relevant to the regulatory action.

In the case of a ban or phase-out, in deciding whether any exemptions should be allowed EPA must also consider "to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the conditions of use if the rule is promulgated."

The TSCA Modernization Act also strikes the "least burdensome" language of current TSCA. Where EPA determines a chemical presents an unreasonable risk, it is to impose requirements "to the extent necessary so that the chemical substance no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed subpopulation.

In deciding what restrictions to impose, the bill retains current TSCA's requirement that EPA must consider the "reasonably ascertainable economic consequences of the rule, including the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health." This broad language would continue to place substantial evidentiary and analytic burdens on the EPA in order to regulate a chemical. Moreover, the bill adds two more mandatory cost-related evidentiary and analytic requirements not in current TSCA:

- EPA must show that any requirements it imposes on a chemical are "cost-effective, except where the Administrator determines that additional or different requirements ... are necessary."
- In deciding whether to impose a ban or effective ban on specific uses of a chemical, and in setting compliance dates, EPA must "determine whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or restriction takes effect."

While the latter of these two requirements does not expressly preclude EPA from banning a use of a chemical if a safer, viable alternative is not available, it comes close, raising concerns similar to those I raised about a House discussion draft introduced in the last Congress.

Collectively, these requirements that must be met for EPA to regulate a chemical would appear to place burdens on EPA comparable to the requirement under current TSCA (struck in the bill) that EPA demonstrate its regulation imposes the "least burdensome requirements."

Relationship to other Federal laws

Under *current TSCA* (Section 9), EPA must consider whether any risks it identifies could be addressed either by another federal agency or by EPA acting under another statute. Various procedures must be followed where EPA so determines.

The Lautenberg Act retains these requirements of current TSCA.

The TSCA Modernization Act of 2015 retains these requirements but adds a new cost-related requirement that EPA would have to meet before taking any regulatory action under TSCA instead of another law EPA administers: "[T]he Administrator shall compare the relative risks, estimated costs, and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk."

This new set of analytic and evidentiary requirements is in addition to TSCA's existing requirement that EPA show that acting under TSCA is "in the public interest" (which currently is determined at the Administrator's discretion).

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