Department of Toxic Substances Control

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Dear Mr. Yeung:

I am writing to you to convey initial comments from the California Department of Toxic Substances Control (DTSC) regarding the proposed Chemical Safety Improvement Act ("the Act"). DTSC is extremely concerned about this bill. DTSC recognizes that the Act includes some positive reforms to the Toxic Substances Control Act ("TSCA"), but at this point, the areas of concern overshadow these improvements. While most of DTSC's concerns center around the Act's preemption provisions, DTSC also has broader concerns regarding the functionality and effectiveness of the Act.

Areas of concern:

- **The expansion of the preemptive effect of EPA action under TSCA.**
    - The Act would broaden vastly the scope and conditions of preemption by TSCA of state and local chemical regulations.
    - There is a need for clarification regarding what constitutes a "prohibition or restriction on the manufacture, processing, or distribution in commerce or use of a chemical substance," in order to clearly define what types of state actions are intended to be preempted under the Act.
        - Industry may argue that a labeling requirement could be considered a restriction on the use of a chemical substance, which is far too broad an interpretation of this phrase.
    - States would be barred from enforcing existing chemical regulations after issuance of a safety determination by US EPA, even when state regulations are consistent with the findings of US EPA's safety determinations.
        - States should be allowed to continue to enforce their regulations until the Administrator for US EPA promulgates a rule establishing necessary restrictions after making a determination.
    - States would be barred from imposing new prohibitions or restrictions on chemical substances that are identified as "high-priority" as of the time the

Administrator of US EPA publishes a schedule for conducting a safety assessment, not as of the time that such a determination is actually made.
        - States should not be barred from imposing regulations on chemical substances for which they have already evaluated the safety and determined that prohibitions or restrictions are necessary to protect public health or the environment merely because the Administrator has released a schedule by which US EPA will conduct its own assessment.
    - The criteria for a state waiver are nearly impossible to meet.
        - The requirement that "compelling State or local conditions" warrant the waiver is unreasonable, as the risks presented by exposure to chemical substances are unlikely to present localized risks.
- **The safety standard to be used in making safety determinations**
    - There is a need for clarification of the definition of "unreasonable risk of harm to human health or the environment," which is central to the regulatory standard of US EPA's safety determination.
- **The lack of deadlines for US EPA actions both in making the initial determinations of high-priority and low-priority chemicals, and in acting upon unreasonable risks that are identified**
    - Proposed language only says that the US EPA Administrator "shall make every effort to complete the prioritization of all active substances in a timely manner."
        - There is conflicting language in Section 4, subparagraph (e)(3)(E)(i) and (ii) under "Identification of High-Priority Substances." These provisions state that the Administrator both "shall" and "may" identify a chemical substance that has the potential for high hazard or exposure as a high-priority substance.
    - Deferring safety determinations until after receipt of additional test data and information may allow the chemical industry to actively stall the assessment process if no deadline is included.
    - There is no proposed deadline by which the US EPA Administrator must promulgate a rule establishing necessary restrictions after making a determination that a chemical substance does not meet the safety standard under current intended conditions of use.

<u>Background:</u>
The Act first requires US EPA to identify all active chemicals, which are those in use in non-exempted products in the last 5 years. These chemicals will represent US EPA's initial list of chemicals, and EPA will then consider existing information, and where more is needed, will solicit this information from the public. EPA is then charged with conducting a prioritization screening of these chemicals. This screening designates chemicals as either low-priority, when they are "likely to meet the safety standard," or high-priority, indicating that they present a high hazard and exposure or high hazard or high exposure. EPA can also prioritize chemicals that lack sufficient information as high-priority.

Once prioritized, the Administrator of US EPA will publish a schedule for the completion of a safety assessment of high-priority chemicals on a chemical-by-chemical basis. The assessments will result in a safety determination by the Administrator as to whether a chemical substance meets the safety standard under the intended conditions of use. The safety standard is defined as "a standard that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance." If there is a determination that there is insufficient information to make this determination, the Administrator may obtain new data by request, rule, testing consent agreement, or order.

If a chemical does not meet the safety standard under current intended conditions of use, the Administrator may impose, by rule, necessary restrictions or prohibitions on use of the chemical, or a ban or phase-out of the chemical. The latter must be based on a cost-benefit analysis.

The Act significantly changes the preemption provisions in TSCA (currently found in section 18). Under TSCA, a state may apply to the Administrator for an exemption from preemption for a state requirement

> "designed to protect against a risk of injury to health or the environment associated with a chemical substance, mixture, or article containing a chemical substance or mixture if (1) compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under [TSCA], and (2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under [TSCA] and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce."

Under the proposed Act, however, States are preempted from enforcing existing requirements, or establishing new requirements, once the Administrator has issued a completed safety determination for a chemical substance, or published a schedule for conducting a safety assessment of a chemical identified as high-priority, respectively. The preemption provision would apply to State requirements that represent "a prohibition or restriction on the manufacture, processing, or distribution in commerce or use of a chemical substance…", as well as certain requirements for the development or test data or information that would produce information similar to that required under section 4, 5, or 6 of the Act.

The Act does include a section on state waivers from the preemption provisions, but the criteria to qualify for such a waiver make obtaining one nearly impossible. The Act provides that if the State "determines in cannot wait until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and determination," the Administrator may provide a waiver from the preemption provisions upon a determination that:

> "(i) compelling State or local conditions warrant granting the waiver to protect human health or the environment;
> (ii) compliance with the proposed requirement of the State or political subdivision of the State does not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;
> (iii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

(iv) the proposed requirement of the State or political subdivision of the State is based on the best available science and is supported by the weight of the evidence; or

(2)(A) the Administrator finds a safety assessment or determination has been unreasonably delayed; and

(B) the State certifies that—

(i) the State has a compelling local interest to protect human health or the environment;

(ii) compliance with the proposed requirement of the State does not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(iii) compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

(iv) the proposed requirement is grounded in reasonable scientific concern."

DTSC is very concerned that the bar has been set too high for obtaining state waivers from the expanded preemption provisions in the Act. The preemption provisions would potentially impact the ability of DTSC to implement certain regulatory responses under the Safer Consumer Products regulations, including product information for consumers, use restrictions on chemicals and consumer products, product sales prohibitions, engineered safety measures or administrative controls, end-of-life management requirements, and advancement of green chemistry and green engineering.

Thank you very much for reaching out to DTSC and allowing us the opportunity to provide input on these important issues.

If you have any questions, please feel free to contact me at (916) 324-7663 or Joshua.Tooker@dtsc.ca.gov

Sincerely,

Josh Tooker
Deputy Director for Legislation
Department of Toxic Substances Control