Discussion Draft – Chemicals in Commerce Act
Highlights

Testing

The Discussion Draft creates a tiered information development system, allowing EPA to obtain the hazard and exposure information it needs to carry out the law without having the agency overwhelmed with unnecessary data and analyses.

- EPA authority to mandate information development is provided for four (4) instances: (1) to perform a determination about the safety of an existing chemical, (2) to ensure compliance with restrictions on new chemicals or new uses of an existing chemical, (3) to review chemicals meant only for export, or (4) to help another federal agency with implementing its own regulations.

- In carrying out these activities, EPA must first consider all the available information about a chemical substance or mixture. If that available information is not conclusive enough to either rule out or demand testing, EPA is authorized to make manufacturers and processors screen that chemical or mixture to ascertain whether a formal test is required. If the screening shows that testing is needed, then EPA may ask for testing of the chemical substance or mixture.

- If EPA needs either screening or testing data on a chemical substance or mixture, EPA can compel it from a manufacturer or processor through promulgating a rule, issuing an order, or entering into a consent agreement. Groups of manufacturers or processors may jointly develop the information to share in the cost.

- EPA is expected to use high quality data, minimize the use of animal testing, and publish the non-confidential information it gathers.

New Chemicals and Significant New Uses

The Discussion Draft maintains the successful elements of existing requirements on new chemicals and new uses of existing chemicals, while also providing a few improvements to it. The Discussion Draft also continues current notice exemptions for chemicals made in small quantities for experimentation, research, analysis, or test marketing; where the substance will exist temporarily and there will be no human exposure; or where (with notice and comment) EPA determines it will not likely result in risk of harm.

- Requires a 90-day advance notice to EPA if a person intends to:
    - Manufacture a new chemical for commercial production
    - Commercially manufacture or process a chemical for a new use, which EPA considers significant, unless they have given EPA 90 notice days before they intend to do it.

- EPA determines by rule whether the new use of an existing chemical is significant
    - EPA may determine that use of a substance as part of an article is a significant new use only where the risk cannot be addressed through requirements placed on the substance
    - EPA publishes receipt of this notice within 5 days of receiving it.

- Requires EPA, within 90 days of receiving the notice of intent, to review the chemical substance described in the notice and, if necessary, request additional information to determine whether exposure to the chemical substance under intended conditions of use is likely to result in an unreasonable risk of harm to human health or the environment.
    - EPA may extend the review period:
        - Up to another 90 days or
        - As long as needed if the manufacturer or processor agrees to the extension in order to develop and submit additional information about the chemical.

- Before EPA's review period ends, it is required to determine whether the new chemical or the significant new use of an existing chemical is likely to pose an unreasonable risk of harm under its intended conditions of use.

- Requires notice to EPA within 30 days of commencement of manufacture for a new chemical substance that is:
    - Not likely to pose an unreasonable risk of harm under its intended conditions of use or
    - Is subject to a rule restricting its use.

- Allows EPA to reconsider a decision about a chemical or its use made under section 5 if EPA receives new information. In that case, the substance or use of the substance is reviewed as an existing chemical under section 6.

Existing Chemicals

The Discussion Draft provides a structure to evaluate, prioritize, review, and, if necessary, regulate a chemical that poses an unreasonable risk of harm to human health or the environment under its intended conditions of use.

Assigning priorities

- Based upon public input, EPA is required to establish a system to designate and list chemicals as either high priority or low priority, with active chemicals (*see* section 8) being given precedence in being assigned a priority.
    - Chemicals with potential for high hazard *and* high exposure are high priority. Those chemicals with high hazard *or* high exposure may be assigned as a high priority.

- Chemicals not likely to result in unreasonable risk of harm to health or the environment under the intended conditions of use are low priority. Low priority chemicals are not subject to further safety review and determination unless redesignated as a high priority.
- EPA may revise priority assignments based on new information.
- Priority designations are subject to notice and comment.
- Low priority designation is subject to judicial review as final agency action.

Safety Determinations

- EPA must determine whether a high priority substance will result in an unreasonable risk of harm to human health or the environment under its intended conditions of use.
  - EPA may require, by promulgating a rule, issuing an order, or entering into a consent agreement, the development of information on hazard, exposures, and uses to help it make its determination.
  - EPA's safety determination must use "best available science, analyze types of exposures (including for subpopulations), incorporate reference parameters, and consider threshold doses.
  - Upon making a safety determination, EPA must publish its findings and rationale.

Restrictions

- If EPA determines that a chemical poses an unreasonable risk of harm to health or the environment under its intended conditions of use, EPA is required to issue a regulation on the chemical substance. This rule, which may apply to mixtures or, if necessary, articles, may contain requirements such as warning labels, use and exposure monitoring, restrictions, phase-outs, or volume limitations on the use of a chemical substance.

- Such restrictions must be proportional to the risks avoided; result in net benefits; be cost-effective; be imposed only when alternatives that materially reduce risk to health or the environment are unavailable; and provide for a reasonable implementation period.

Information Collection and Reporting

The Discussion Draft modernizes the way information is reported to and by EPA under TSCA. The language requires EPA to delineate its public reporting of all chemicals that have ever been in U.S. commerce and those that are currently active. It also compels EPA to obtain greater amounts of use information about chemicals to help the Agency make better decisions.

- Requires EPA to develop guidance concerning the types and detail of information required as well as the manner by which manufacturers and processors can report use and exposure information on chemicals that are active in commerce.

- EPA must develop a separate confidential list of information that it keeps internally and a public list of information on chemicals that is not protected from disclosure under the Discussion Draft.

- Requires EPA to delineate between chemicals actively in commerce and those that are no longer in commerce – or inactive – on the TSCA Inventory.

Exports

The Discussion Draft simplifies the export provisions of TSCA while maintaining their current applicability.

- EPA may require an exporter to notify EPA annually when intending to export a new or existing chemical substance or mixture that is subject to a restrictive rule under section 5 or 6.

- Exporters must notify EPA if exporting a substance or mixture subject to treaty export notification requirements.

Imports

The Discussion Draft modernizes and conforms the provisions of TSCA related to imports to the changes made to the underlying law by the Discussion Draft.

- Requires anyone importing a chemical substance or mixture into the United States – which EPA has designated as a high priority chemical or regulated under sections 5 or 6 – to certify to the Department of Homeland Security (U.S. Customs) it is included on the section 8 list or is exempt from inclusion on that list.

- DHS must refuse entry to a chemical if its importation would violate a restriction on section 5 or 6.

Confidential Information

The Discussion Draft clarifies the protection of chemical identity under TSCA. It also provides several new categories of persons who may obtain confidential business information and the reasons that EPA may disclose protected information to them.

- EPA may not disclose information exempt as a trade secret under the Freedom of Information Act, as well as information describing manufacturing, processing or distribution; marketing and sales information; constituents of a mixture;

information on use, function or application of a chemical substance or mixture in a process, mixture or product; or specific production or import volumes.

- EPA may not disclose the specific identity of a chemical substance (name, formula, CAS number) if the person seeking protection from disclosure submits written documentation establishing that:
    - They take measures to protect the confidentiality of the chemical's identity;
    - Disclosure is not required under another Federal law;
    - Disclosure of the chemical's identity harms a competitive position; and
    - The information cannot be discovered though reverse engineering.

- The applicant seeking information protection must establish the time period for which he claims protection and provide a generic name that may be disclosed.

- EPA may not protect from disclosure:
    - Health and safety information on a substance offered for commercial distribution; including a notice of substantial risk pose by a chemical
    - Information required by EPA to be developed pursuant to section 5 or section 6 – unless specific elements of it are protected
    - General information describing ranges of volumes in which the chemical is manufactured or other types of information customarily shared with the general public or within the industry

- Exceptions to EPA's requirement to protect the information from public disclosure include sharing protected information with:
    - A U.S. employee or contractor carrying out official duties
    - A State that agrees to protect the information in the same manner as EPA
    - A health professional who needs the information for diagnostic and treatment purposes and:
        - In non-emergency cases, agrees beforehand to protect the information.
        - In emergency cases, no advance notice is required and the written agreement to protect the information may follow receipt of the information.

- EPA may disclose confidential information to protect health or the environment or to the extent necessary to avoid impairing a proceeding under TSCA.
- Use of the information for an unauthorized purpose or forwarding to an unauthorized person would be punishable as a prohibited act under TSCA.

- EPA would be required to protect the information until it has been publicly disclosed through another means or it longer meets the criteria in section 14.

- Persons whose information would be released by EPA (other than to government officials or health care professionals) would receive 30 day notice before it's released.

    - When information is released to health officials in a non-emergency situation the notice would be 15 days.

- When it's not feasible for EPA to review each confidentiality claim for compliance with section 14, EPA may sample.

- An EPA decision to deny or limit a confidentiality claim would be reviewable in federal district court. Information in dispute may not be disclosed pending court proceeding.

Penalties

The Discussion Draft increases the penalties for violations of TSCA.

- Civil penalties for violation of TSCA are increased from $25,000 to $37,500 per day for each violation.

- Criminal penalties are increased from $25,000 to $50,000, per day for each violation.

- A new penalty is added for persons who knowingly violate TSCA and know in doing so that they are placing another person in imminent danger. This penalty is a fine of $250,000, imprisoned for 5 years, or both.

Preemption

The Discussion Draft preserves authority of states to ban chemicals until the point when EPA determines that the chemical is not likely to cause an unreasonable risk or promulgates a rule restricting the chemical.

- The discussion draft would also preempt state or local law:
    - that requires development or submission of information on a chemical substance, mixture, or article, or its intended conditions of use that EPA has required under section 4, 5, or 6;
    - once the review period for a new chemical has expired;
    - from requiring use notification for a chemical if EPA has required notification under section 5;
    - from placing requirements on chemicals that EPA determined prior to enactment of the Chemicals in Commerce Act pose no unreasonable risk or regulated under sections 5 or 6.

- The discussion draft would preserve:
    - State or local laws adopted pursuant to any other Federal law;
    - actions under State law for personal injury, death, or property damage.

Policies, Procedures, and Guidance

The Discussion Draft adds language to implement the new requirements of the Draft and reinforce the importance of high quality science in implementing its provisions.

- EPA would be required, within one year of enactment, to establish policies, procedures, and guidance needed to implement the Act.
    - The policies, procedures, and guidance must employ and rely upon best available science and risk assessment principles and methodologies, be of high quality, reliable, and produced according to validated methods and processes; and address strengths and limitations of test design and reliability of test methods.

- EPA must require good laboratory practices, scientifically reliable test methods, standardized protocols, and consistent data evaluation procedures.

- EPA must describe the quality and limitations of information and its basis for relying on it.

- EPA must use the best available science (which maximizes quality, objectivity, and integrity of information; uses studies based on sound scientific practices; applies valid, relevant and public information; and enables assessment of risks and uncertainties) in making decisions under section 4, 5, and 6.

Preservation of authority

The Discussion Draft preserves existing TSCA regulations and decisions not otherwise amended by the Draft.

- Except as provided by the Chemicals in Commerce Act (CICA), nothing in CICA would alter the authority of EPA under TSCA as in effect when CICA is enacted, or the continued application or validity of any EPA action under TSCA prior to enactment of CICA.