



NATIONAL CONFERENCE
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Section By Section of H.R. _____, the "Chemicals in Commerce Act" *DISCUSSION DRAFT*

Section 1. Short Title; Table of Contents; References.

Specifies that any amendment or repeal language contained in this bill shall be construed to mean an amendment or repeal of a section or provision of the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*)(TSCA). Interrupt

Section 2. Findings and Purpose.

Amends TSCA findings and purpose and creates new findings that chemicals in commerce should be safe for their intended use; that these chemicals should be managed by a federal scheme that reflects modern science, technology and knowledge; that public confidence in the federal chemical regulatory program is important; and innovation in the development of new chemical substances should be encouraged to promote job creation, improve products, reduce risk, stimulate the economy and promote interstate commerce.

Section 3. Definitions.

Creates new definitions under TSCA to include defined terms such as "best available science," (the use of reliable scientific data and risk assessment) and "potentially exposed subpopulation" (those people at greater risk of harm from exposure to a chemical substance than the general population), amends the existing definition of "intended conditions of use" to mean the circumstances under which a chemical substance is intended or reasonably anticipated to be manufactured, processed, distributed in commerce, and used.

Section 4. Testing of Chemical Substances and Mixtures.

Requires manufactures to develop new hazard and exposure information for a chemical substance if the EPA administrator needs it to perform a safety determination, ensure compliance with a rule under Section 5(c)(5), Section 6(f), or Section 12(a)(2) of this bill, or for the implementation of any other federal law.

- Allows the administrator to carry out this section by promulgating a rule, entering into a consent agreement, or issuing an order, provided that the administrator first consider available information including exposure potential and screening level hazard and exposure information.
- Calls for any rule, consent agreement or order to identify the chemical substance for which information is required, may include protocols and methodologies for the development of

information for the chemical substance, and provide a reasonable period for submission of this information.

- Permits the Administrator to consider the cost of any testing or methodologies as well as the reasonably foreseeable availability of facilities and personnel needed to perform the testing.
- Authorizes the Administrator to require the development of screening level hazard and exposure information if the available information is insufficient for the Administrator to make a decision, and allows the Administrator to request additional information.
- Requires the Administrator to issue a statement when promulgating a rule, consent agreement or order that identifies the need intended to be met, explaining why reasonably available information is inadequate to meet that need, and explaining the basis for a decision that requires the use of vertebrate animals.
- Requires the Administrator to issue an explanatory statement where an order is issued that explains why there is an order and not a rule. Delineates the required components of this explanation (See, Section 4(b)(2)(B)).
- Calls for the minimizing of the use of vertebrate animals in the testing of chemical substances or mixtures and encourages alternative methods of testing.
- Prohibits the Administrator from requiring the development of information regarding a chemical substance or mixture more than 180 days after the manufacturer has begun to produce said chemical substance or mixture.
- Mandates that in the instance of developing information from epidemiologic studies or workers, the Administrator must consult with the Director of the National Institute for Occupational Safety and Health.
- Requires the Administrator to initiate the appropriate action within 180 days of receipt of any information that leads to the determination that a chemical substance presents or will present a significant risk of serious or widespread harm to human health. There is a 90 day extension period permitted. This section also requires the Administrator to publish findings of no harm in the Federal Register.

Section 5. New Chemicals And Significant New Uses

- Requires that before a person can manufacture a new chemical substance, that person must submit to the Administrator a notice of intent to manufacture a new chemical substance or that person may not proceed.
- Places the decision as to what constitutes a new use solely on the Administrator. The Administrator's decision that a chemical substance is a significant new use is determined by a rule that considers:
 - The projected volume of manufacturing and processing of the chemical substance;
 - The extent to which a use changes the type or form of exposure to humans or the environment to the chemical substance;
 - The extent to which a use increased the magnitude and duration of exposure of humans or the environment to the chemical substance; and

- The intended conditions of use.
- Allows the administrator to determine that the use of a chemical substance as part of an article is a significant new use but only when the articles are likely to be in United States commerce, an unreasonable risk of human or environmental harm is present, and placing requirements on the articles is required because such risks cannot be adequately addressed through requirements placed on the chemical substance.
- Mandates that the administrator must publish notices of intent to manufacture a new chemical substance in the Federal Register not later than five business days after receipt of the notices. The information in the Federal Register must include the identity of the chemical substance and the intended conditions of use. The administrator must also maintain publicly accessible lists of each chemical substance for which notice has been received and each chemical substance for which such review period has expired since the last publication of such list.
- Requires the administrator to make a determination of significant new use not later than 90 days after receipt of a notice to manufacture a new chemical substance. The administrator must conduct a review of the notice, develop a profile of the chemical substance, and if necessary request additional information. It is up to the Administrator's discretion to extend the review period for good cause. The administrator may also consider previously submitted information.
- Specifies that before the end of the 90 day review period or any extension of such review period, the administrator must make a determination that exposure to the chemical substance under the intended conditions of use:
 - Is likely to result in an unreasonable risk of harm to human health or the environment and take appropriate action; or
 - Is not likely to result in an unreasonable risk of harm to human health or the environment and the review period shall expire without the imposition of restrictions.
- Permits the person who submitted the notice of new chemical substance to commence commercial production of the chemical substance unless the administrator has found an unreasonable risk of harm to humans or the environment and has imposed a requirement or restriction that prohibits the manufacture of such chemical substance.
- Requires the administrator to impose the following requirements or restrictions if a determination of unreasonable risk is made before the end of the applicable review period:
 - A requirement or restriction that the chemical substance be marked with or accompanied by clear and adequate warnings and instructions with respect to distribution in commerce or use or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the administrator;
 - A requirement or restriction that manufacturers or processors of the chemical substance make and retain records of the processes used to manufacture or process the chemical substance, monitor specific uses of or exposures to the chemical substances,

or develop additional information that is reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, or use of the chemical substance.

- A restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce.
 - A requirement to restrict or ban the manufacture, processing or distribution in commerce of the chemical substance for a particular use, a particular use at a concentration in excess of a level specified by the administrator, or for all uses.
 - A restriction in the quantity of the chemical substance that may be manufactured processed or distributed in commerce for a particular use or a particular use at a concentration in excess of a level specified by the administrator.
 - A requirement to restrict or ban a method of commercial use of the chemical substance.
 - A requirement directing manufacturers or processors of the chemical substance to give notice of unreasonable risks of harm to distributors in commerce and to the extent reasonably ascertainable to other persons in the chain of commerce in possession of the chemical substance.
- A person who has submitted notice and commences manufacturing of a new chemical substance must submit a notice of commencement to the administrator not later than 30 days after the date on which production was commenced and which identifies the manufacturer's name and date of manufacture. A notice to manufacture may be withdrawn.
 - Allows the administrator to conduct additional evaluations on chemical substances on the publicly accessible list when (s)he becomes aware of new information regarding the chemical substance that provides a reasonable basis for reconsidering it.
 - Exempts chemical substances that are to be manufactured or produced in small quantities as defined by rule by the administrator solely for the purpose of scientific experimentation or chemical research from the notice requirements of Section 5.
 - Exempted manufacturers or processors shall notify all persons engaged in this activity in accordance with the Administrator's guidelines.
 - Exempts at the discretion of the administrator a chemical substance that will be produced for test marketing purposes provided the person satisfactorily shows that the chemical substance is not likely to result in an unreasonable risk of harm to human health or the environment and all restrictions deemed necessary by the administrator are incorporated.
 - Upon receipt of a request to test market a chemical substance, the administrator must publish notice of the request in the Federal Register and provided interested parties the opportunity to comment.

- The administrator has 45 days to either deny or grant the request to test market and publish the decision in the Federal Register.
- Provides that the administrator has discretion to exempt anyone from the provisions of Section 5 if (s)he determines that production, manufacturing, use and distribution in commerce or any combination thereof presents a low risk of harm to human health or to the environment. This decision must be made by rule with appropriate notice and the opportunity to comment.
- Permits the administrator, by rule, to make the requirements of Section 5 inapplicable to the production or manufacture of a chemical substance which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture, or to which there is no, and will not be human or environmental exposure.
- Permits the administrator, by rule, to make the requirements of Section 5 inapplicable to the manufacture or processing of any byproduct chemical substance produced without a separate commercial intent during the manufacture, processing, use or disposal of another chemical substance or mixture if:
 - It is not used for commercial purposes; or
 - The only intended commercial purpose is for burning as fuel, disposing as a waste, including in a landfill or for enriching soil; or extracting, by reaction or otherwise a chemical substance to recycle or reclaim.
- Declares that a combination of chemical substances physically combined without a chemical reaction shall not be a new chemical substance for purposes of Section 5.

Section 6. Existing Chemicals

Amends TSCA to insert a new section.

- Requires the administrator to establish a risk-based process for designating, based on the weight of the best available science, chemical substances as either high priority or low priority.
 - This process must be established not later than 1 year after enactment of this act.
 - The administrator must provide notice and the opportunity to comment on this process.
- Defines high priority chemicals as those that have the potential for high hazard or high exposure.
- Defines low priority chemicals as those that are not likely to result in unreasonable risk of harm to human health or the environment under the intended conditions of use.
- Encourages the administrator to make timely decisions on the priority of a chemical, but allows her/him to defer designations in order to provide interested person an opportunity to submit additional information not previously available to the administrator.

- Requires the administrator to publish and update “from time to time” a list of chemical substances that tells whether a chemical is high or low priority and indicating those for which a safety determination has been completed.
- Outlines the factors for assigning priorities. These must include:
 - The hazard and exposure potential including information from authoritative governmental entities;
 - The specific uses and exposures that are significant to the risk of harm to humans and the environment and the intended conditions of use or changes in the conditions of use of chemical substances;
 - Evidence and indicators of exposure to humans or the environment from a chemical substance;
 - Volume of a chemical substance manufactured or processed;
 - Whether the volume has significantly increased or decreased since a previous report or date of notice;
 - The availability of information about potential hazards and exposures needed for conducting a safety determination; and
 - **The extent of federal or state regulation of a chemical substance or the extent of the impact of state regulation of that chemical substance on the United States with existing federal or state regulation as a factor in designating a chemical substance as a low priority.**
- Stipulates that chemicals designated as low priority are not subject to a safety determination, and unless redesignated as a high priority, shall be considered not likely to result in an unreasonable risk of harm to humans or the environment.
- Requires priority determinations to be subject to notice and comment.
- Permits the administrator to revise the priority designation based on new information.
- Requires that the administrator periodically review priority designations (does not provide a time period for this).
- Provides that the designation of a chemical as high priority shall not affect the manufacture, processing, distribution, use or disposal of the chemical substance or regulation of those activities.
- **States that the administrator’s determination that a chemical is high priority is not a final agency action subject to judicial review.**

- Mandates that the administration shall make safety determinations based on the best available science related to health and environmental considerations and in accordance with the weight of the scientific evidence regarding whether:
 - The chemical substance designated as high priority doesn't result in an unreasonable risk of harm to humans or the environment under its intended use;
 - The chemical substance designated as high priority will result in an unreasonable risk of harm to humans or the environment under its intended use, in which case the Administrator shall impose one or more restrictions delineated above; or
 - Additional information is required to make a determination of risk.
- Requires that the administrator must do the following in making safety determinations:
 - Afford greater weight to scientific evidence that meets certain criteria;
 - Use the best available science and integrate and assess information on hazards;
 - Analyze exposure to the chemical substance for the specific uses that are significant to the risk of harm;
 - Describe the weight of the scientific evidence for observable biological effects;
 - Incorporate reference parameters that may be appropriate with regard to a specific chemical substance; and
 - Consider whether the weight of the evidence of the best available science supports the identification of threshold doses of a chemical substance below which no adverse effects can be expected to occur.
- Permits the administrator to request additional information to make a safety determination and may defer making this determination until after such information is received.
- Requires safety determinations to be published.
- Requires that when a chemical substance has an unreasonable risk of harm, the Administrator must promulgate a rule. The rule can apply to both mixtures containing the chemical substance or to articles as long as they are specifically identified.
 - Rules promulgated under this section must include one or more of the following:
 - A requirement that the chemical substance be marked with or accompanied by clear and adequate warnings and instruction with respect to its use and distribution in commerce;
 - A requirement that manufacturers and processors of the substance make and retain records of the manufacturing process, monitor specific

uses of the substance, or develop additional information to comply with this section;

- A restriction on the quantity of the chemical substance that may be manufactured;
 - A requirement to restrict, ban or phase out the manufacture or distribution of the substance for a particular use, for all uses, or for a use at a concentration in excess of a level specified by the administrator;
 - A restriction on the quantity of the chemical substance that may be manufactured or distributed in commerce for a particular use, for all uses, or for a use at a concentration in excess of a level specified by the Administrator;
 - A requirement to restrict, ban or phase out a method of commercial use of the chemical substance;
 - A requirement directing manufacturers of the substance to give notice of unreasonable risks of harm to distributors in commerce of the substance and to the extent reasonably ascertainable, to other persons in the chain of commerce.
- Mandates that the administrator must determine that any requirements or restriction on a chemical substance under this section are proportional to the risks stated in the safety determination, will result in net benefits, and are cost-effective. The administrator may impose requirements or restrictions under this section only when there are economically feasible alternatives that materially reduce risk available, and must provide for a reasonable transition period for implementation.
 - States that a determination of no unreasonable risk is a final agency action.
 - States that a determination of unreasonable risk is a final agency action on the date or publication of the final rule promulgated under this section.

Section 7. Imminent Hazards

- Permits the administrator to initiate a civil action in the appropriate U.S. District Court for seizure of an imminently hazardous chemical substance or mixture, relief against any person who manufactures or distributes such substance, or seizure and relief.
- Allows the administrator to commence a civil action even when there is an existing consent agreement, a prior decision by the administrator, a rule or order, or a pending judicial proceeding under any other provision of this Act.

Section 8. Information Collection and Reporting.

- Requires the administrator to promulgate rules establishing reporting requirements for manufacturers and processors to carry out Section 6 of this act not later than two years after enactment.
- Stipulates that the administrator must develop guidance relating to the information required to be reported that includes the appropriate level of detail necessary to be reported, and the manner by which voluntary reporting of exposure and risk may be done.
- Exempts from this section chemical substances that are extracted by reaction or otherwise from another chemical substance for the purpose of recycling or reclaiming.
- Provides for specific nomenclatures for certain substances.
- Mandates manufacturers notify the administrator when it has manufactured or processed a chemical substance that has been placed on the list required by this act during the five-year period prior to the date of enactment. The administrator shall outline how this is to be done by rule and by providing guidance relating to that rule.
- Requires a manufacturer submitting notice to state whether the chemical substance at issue is confidential.
- Requires the manufacturer submitting notice to retain a record of the information submitted to the administrator for five years beginning on the last day of the submission period.
- Defines “active substance” as a chemical substance that has been manufactured or processed at any point during the five years prior to enactment of this act if the chemical substance was produced before enactment, or 4 years after the enactment of this act if the chemical substance was manufactured after enactment.
- Defines “inactive substance” as a chemical substance that has not been manufactured or processed at any point during the five years prior to enactment of this act if the chemical substance was produced before enactment, or four years after the enactment of this act if the chemical substance was manufactured after enactment.
- Requires notice to be sent to the administrator to change inactive to active status. The administrator must then update the list required by this act.

Section 9. Relationship to Other Federal Laws.

- Reconciles the requirements of this act with other existing federal laws.

Section 10. Research, Development Collection, Dissemination, and Utilization of Data.

- Technical changes only.

Section 11. Inspections and Subpoenas.

- Technical changes only.

Section 12. Exports.

- Makes technical changes and establishes notice procedures for intent to export a chemical substance to a foreign country.

Section 13. Imports.

- Establishes notice procedures for intent to import chemical substances into the U.S. from foreign countries.
- Permits the secretary of Homeland Security to refuse entry into the U.S. if such substance would violate a rule, order or consent decree under this act. Certain exceptions apply.

Section 14. Confidential Information.

- Prohibits the administrator from disclosing certain information except as provided by this section. People claiming confidentiality must substantiate their claim with written documentation as to why.
- Exceptions include information related to health and safety.
- **Grants discretionary authority to the administrator to share information otherwise protected under this section with states upon written request for the purpose of development, administration, or enforcement of a law if the state recipient agrees in writing to take appropriate steps and has adequate authority to maintain the confidentiality of the information, and the administrator notifies a person claiming protection of the information that the information will be disclosed to a state.**
- Grants discretionary authority to the administrator to share information with health professionals who work for a state agency or a treating physician or nurse in a non-emergency situation if such person makes a written request and the person agrees in writing not to use the information for any purpose other than diagnosis and treatment.
- Contains other provisions for disclosure of information on a limited basis.

Section 15. Prohibited Acts.

- Makes technical amendments

Section 16. Penalties.

- Establishes various fines for violators of this act.

Section 17. Preemption.

- Prohibits states and local governments from establishing or continuing to in force a law or regulation that, for the purpose of regulating chemical substances, mixtures, or articles for intended conditions of use:
 - Requires the development or submission of information that the administrator has required under sections 4, 5, or 6 of this act or that relate to a chemical substance, mixture or article and its intended conditions of use with respect to which the Administrator has completed a safety determination;
 - Prohibits or restricts the manufacture, processing, distribution in commerce, or use of a chemical substance, mixture or article for its intended conditions of use if the administrator has determined under Section 5 of this act that the chemical substance, mixture or article is not likely to result in an unreasonable risk of harm to human health or the environment or has determined that under Section 6 of this act the chemical substance, mixture or article is not likely to result in an unreasonable risk of harm to human health or the environment;
 - States may not regulate chemical substances if the administrator has promulgated a rule, entered into a consent order, or issued an order under Sections 5 or 6 of this act relating to such chemical substance;
 - States may not regulate chemical substances if the administrator has designated such substance to be a low priority substance pursuant to Section 6 of this act.
 - Prohibits states from regulating chemical substances, mixtures, or articles when the review period under Section 5 has expired.
 - Requires the notification of a use of a chemical substance, mixture or article with respect to which the administrator has required notification pursuant to Section 5;
 - Includes any requirement with respect to a chemical substance, mixture, or article or its intended conditions of use if the Administrator, before the enactment date of this act, has promulgated a rule, entered into a consent agreement or issued an order or allowed the expiration of a significant new use review period under Section 5.
 - In the case of a state law or regulation that was not in effect on the date of this act's enactment and regulates a chemical substance, takes effect on or after the date that the administrator determines such substance to be a low priority under Section 6.
- Exempts state laws or regulations that are adopted or authorized pursuant to any other Federal law.
- Allows causes of action under state law for damages or equitable relief alleging personal injury, death, or property damage arising from exposure to a chemical substance or mixture.

Section 18. Judicial Review.

- Permits the filing of an action for judicial review in the U.S. Court of Appeals for the District of Columbia, in the circuit in which the person resides, or in the circuit in which the principal place of business of the person is located, not later than 60 days after the date of the promulgation of a rule under Sections 4, 5, 6, or 8. The U.S. Courts of Appeals shall have exclusive jurisdiction.
- Title 5 of the U.S. Code section 706 shall apply to review of a rule, order, or final agency action under this section except in certain instances such as a rule under section 4, 5, or 6 of this act. The standard of review is also changed under this section.

Section 19. Citizens' Petitions.

- Amends TSCA to provide for de novo proceedings to initiate a rule under section 4, 6 or 8 of this Act or an order issued under sections 4 or 5 of this act.
 - Standard of review is preponderance of the evidence- the petitioner must show by a preponderance of the evidence that a proceeding is warranted.
 - The court may permit the administrator to defer initiating the action requested by the petitioner until such time as the court prescribes if the court finds that the extent of risk to human health or the environment is less than the extent of those risks to human health or the environment with respect to which the administrator is otherwise taking action under this Title, and there are insufficient resources available to the administrator to take the action requested by the Petitioner.

Section 20. National Security.

- Makes technical amendments.

Section 22. National Security.

- Requires the administrator to waive compliance with any provision of this act upon a determination by the president that the waiver is necessary in the interest of national security. In this instance, the administrator shall publish notice in the Federal Register of waivers granted for national security reasons unless the president deems this notice to run counter to national security interests.

Section 21. Studies.

- Makes technical changes.

Section 22. Policies, Procedures, and Guidance.

- Adds a requirement that not later than one year after the enactment of this act, the administrator shall, after providing public notice and an opportunity to comment, establish all policies, procedures and guidance necessary to implement the amendments made to TSCA by this act. Such policies, procedures and guidance shall rely upon the best available science and best available risk assessment principles and methodologies.

- Requires the administrator to follow certain procedures and use only the best available data to produce high quality information.

Section 23. Technical Amendment.

Section 24. State Programs.

- Amends TSCA , 15 U.S.C. Section 2627 by striking subsections (a) and (d). This section would eliminate grants to states for the establishment and operation of programs to prevent or eliminate unreasonable risks within the states to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator is unable or is not likely to take action under this chapter for their prevention or elimination and eliminates the appropriation to state to do this work.

Section 25. Authorization of Appropriations.

- Repeals 15 U.S.C. Section 2628 which states, “There are authorized to be appropriated to the administrator for purposes of carrying out this chapter \$58,646,000 for the fiscal year 1982 and \$62,000,000 for the fiscal year 1983. No part of the funds appropriated under this section may be used to construct any research laboratories.”

Section 26. Annual Report.

Section 27. Preservation of Authority.

- Provides that nothing in this act shall amend, alter, or affect the administrator’s authority under TSCA that was in effect before the enactment of this Act.

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