Safe Chemicals Act Section-by-Section

Sec. 1. Short title.

"Safe Chemicals Act of 2010."

Sec. 2. Purpose.

To ensure that risks from chemicals are adequately understood and managed.

Sec. 3. Findings, Policy, and Goal.

Amends section 2 of existing law to reflect the findings, policy, and goal of this Act.

Sec. 4. Definitions.

Amends several definitions in the existing law and adds other definitions used under this Act.

Sec. 5. Minimum Data Set and Testing of Chemical Substances and Mixtures

Amends section 4 of existing law to mandate industry submission of sufficient safety information for EPA to make a safety standard determination on chemicals. The Agency must issue a rule or rules defining the minimum data set for every chemical within 1 year of enactment. Industry must submit the minimum data set within 18 months of the chemical being placed on the priority list for existing chemicals, or as part of a pre-manufacture notice for new chemicals.

The test order and test rule authority in 4(b) streamlines and broadens EPA's existing authority to require additional testing to obtain data on chemicals. Section 4 also allows EPA to obtain samples of chemical substances so that the Agency can conduct high throughput screening and other advanced testing methods.

In order to avoid duplicative testing, the bill maintains the exemptions in current law. Section 4(d) allows one company to conduct toxicity testing on behalf of other companies. In order to avoid unnecessary testing, the data set may be tailored to specific chemicals or category of chemicals.

Sec. 6. Manufacturing and Processing Notices

Amends section 5 of existing TSCA to require more upfront data on the safety of new chemicals and restrict market access for chemicals that do not meet the safety standard. This section also maintains a pathway for expedited safety review for some new safer chemicals. The bill allows these new chemicals to enter the market only if the manufacturer can prove to EPA that the substance does not, and likely will not, meet *any* of the criteria that indicate potentially high risk. However, if the new chemical meets any of the priority criteria, then the manufacturer must demonstrate that the substance meets the safety standard.

New uses of an existing chemical that has not yet undergone a safety determination require notice to EPA. New uses of an existing chemical that has already undergone a safety determination require a notice, updating of the minimum data set, and a finding by EPA that the chemical will continue to meet the safety standard when the new use is considered.

EPA has the authority under section 5 to determine that a new form of a chemical substance—through nanotechnology, for example—is a new chemical or a new use, and, in the case of a new use, to establish a process for approving the chemical for the market.

Sec. 7. Prioritization, Safety Determination, and Risk Management

Amends section 6 of existing law to set out the process for prioritizing chemical substances, conducting safety standard determinations, and managing risk from substances that do not meet the safety standard. This section places the burden on industry to demonstrate the safety of a chemical. EPA's primary function under this bill is to determine whether the data submitted by industry demonstrates that the chemical is safe. The safety standard determination will apply only to the uses evaluated in the determination with any conditions, and any other use of the substance or use in violation of conditions specified are unlawful. EPA may grant exemptions for uses that are vital to our economy and national security.

The process for prioritizing, assessing, and approving or restricting chemicals operates as follows:

- **Prioritizing Chemical Substances for Safety Determination.** Based on available information, including data collected under sections 4 and 8, EPA must, within 18 months of enactment, publish a list of 300 priority chemicals for safety determination. The Agency must then add chemical substances to the list annually to ensure that a minimum of 300 chemicals are listed, and consider petitions to add chemicals. The purpose of the priority list is to signal which chemicals substances will next be assessed for safety.

  The bill instructs EPA to select chemicals for the priority list based on criteria that indicate environmental or health risk. After all the substances that meet any of the priority criteria have been prioritized and assessed, EPA will continue to add substance to the list based on likelihood of posing health or environmental risks. EPA is to review all chemicals for safety within fifteen years.

- **Submission of the all data supporting the safety determination.** Within 18 months of the placement of a chemical on the priority list, all manufacturers and processors must submit the minimum data set for that chemical substance. Within 30 months of placement on the priority list, industry must submit to EPA the package of specific uses to be evaluated, any proposed conditions, and all supporting information to demonstrate that the chemical meets the safety standard. This includes any information not previously submitted under the minimum data set or section 8, any data required under section 4 test orders, or any data which industry believes will be necessary to demonstrate safety. Applications for critical or essential use exemptions may be submitted at this time.

If a manufacturer or processor fails to meet the deadline for submitting information described above, EPA may act to immediately to prevent that party from manufacturing or processing the chemical.

- **Safety Determination**. Within 6 months of receiving the complete data set required within 30 months of the chemical's placement on the priority list, EPA must determine whether industry has demonstrated that a chemical meets the safety standard. EPA's determination applies only to the specific uses evaluated in the safety determination, and the Administrator may place conditions on uses or require other risk management actions to ensure the chemical substance meets the safety standard.

  If EPA misses the deadline for making the determination, all manufacturers or processors must immediately inform their customers that EPA has not been able to find that the chemical meets the safety standard.

Sec. 8. Imminent Hazards

Amends section 7 of the existing law to authorize the Administrator to initiate a judicial proceeding or issue orders as necessary to protect health or the environment from a chemical substance or mixture or any article containing such a substance or mixture that "may present an imminent and substantial endangerment to health or the environment." This section will ensure the Administrator may act at any time to prevent or mitigate an imminent and substantial endangerment, regardless of whether the Administrator has issued a safety determination under section 6.

Sec. 9. Reporting and Retention of Information

This section amends section 8 of the existing law to impose an automatic statutory obligation to submit a broad range of *existing* data, including all existing data on health and environmental effects that has not previously been submitted to EPA, within one year of enactment. Industry must update those data every three years, or if significant new safety-related data becomes available. The section resets EPA's inventory to provide a more accurate picture of the number and types of chemicals in commerce.

The section also requires EPA, within 5 years of enactment and using available information, to develop and publish a list of all chemicals in commerce that categorizes each such chemical. EPA must promptly update the categorizations based on receipt of the minimum data sets required of manufacturers under the bill, or any other information received by EPA that alters a chemical's category assignments.

Sec. 10. Relationship to Other Federal Laws

This section amends section 9 of current law to strengthen EPA's ability to request that other agencies take action within that agency's jurisdiction to reduce risks from chemical substances that fail to meet the safety standard, or would fail to meet the standard without risk management actions. The Administrator is authorized to take action under this Act should another agency not take needed action.

When acting to control workplace exposures, the bill requires that any such action be implemented in a manner that is consistent with the industrial hygiene hierarchy of controls.

Sec. 11. Inspections and Subpoenas

Amends section 11 of existing law to clarify and strengthen EPA's authority to conduct inspections, gather information, and issue warrants for the purposes of administering or enforcing the Act. The authority to conduct inspections applies to all chemical substance, mixtures or articles subject to the Act, to any premises or conveyances containing such substances, and to any place where records are held. The Administrator is authorized to obtain samples of chemical substances, mixtures, articles, containers and labeling, and to require development of analyses and other information, and to obtain and execute warrants.

Sec. 12. Exports

Amends section 12 of the existing law to ensure this Act's protections of health and the environment apply to exports of chemical substances, mixtures or articles that are subject to actions under sections 4, 6 and 7 of this Act. To ensure information about exports is available, notice must be provided to the Administrator, and the Administrator must provide notice to the government of the foreign country.

Sec. 13. Entry into Customs Territory or the United States

Amends section 13 of existing law to require that the Secretary of Homeland Security refuse entry into the customs territory of the United States of any chemical substance, mixture or article that fails to comply with any rule or order in effect under this Act.

Sec 14. Disclosure of Data

Amends current section 14, which governs claims of Confidential Business Information (CBI), to require upfront justification for CBI claims, require EPA to review and make a determination on all CBI claims, require that confidentiality expire after a certain period of time not to exceed five years, provide for greater sharing of CBI between governments, and provide access for workers to information on the chemicals to which they are exposed in the workplace.

Sec. 15. Prohibited Acts

Amends section 15 of the existing law to make clear that it is unlawful to fail or refuse to comply with any rule, order, prohibition, restriction, or other requirement imposed by this Act or by the Administrator under this Act or to make a false submission under this Act.

Sec. 16. Penalties

Amends section 16 of the existing law to increase civil and criminal penalties and expand procedures for assessing penalties against persons who violate a rule, order, or provision of this Act. Civil penalty actions may be commenced in US District Courts or through administrative

proceedings, and civil penalties are increased. Any knowingly violation is subject to increased criminal penalties, and penalties are increased further for any knowing violation that places another person in imminent danger of death or serious bodily injury.

Sec. 17. Specific Enforcement and Seizure.

Amends section 16 to provide the Administrator with authority to commence a civil action in the appropriate US District Court to compel compliance with any rule, order of provision of the Act. The Administrator's authority to enforce the Act includes the authority to seek civil or criminal penalties, to enjoin violations, and to order compliance through administrative proceedings**.**

Sec. 18. Preemption.

Amends section 18 of the existing law to make clear that provisions of any law of a State or political subdivision of a State relating to any chemical substance or mixture, or any article that contains a chemical substance or mixture which are more stringent than provided under this Act are not preempted.

Sec. 19. Judicial Review.

Amends section 19 of the existing law to ensure that agency action taken under this Act is subject to the same standard of review as other agency action in accordance with the Administrative Procedure Act, expressly replacing the existing standard.

Sec. 20. Citizen's Civil Action.

Amends section 20 of existing law to clarify where citizen suits are permitted in light of the changes to other sections of the existing law.

Sec. 21. Citizens' Petitions.

Amends section 21 of existing law to clarify where citizen petitions are permitted in light of the changes to other sections of the existing law.

Sec 22. Employment Effects.

Amends section 22 of existing law to clarify when evaluation is required and the relationship between this section and other provisions of the Act.

Sec. 23. Administration of the Act.

Amends section 26 of the existing law to allow EPA to collect user fees from industry for administration of the Act.

Sec. 24. State Programs.

Sec. 25. Authorization of Appropriations.

Reorders several sections of the existing law, and amends the appropriations section to authorize sums necessary to carry out EPA's authorities under TSCA. Amends section 28 of the existing law to require EPA to establish a process to coordinate with state governments on efforts to manage risks from chemicals.

Sec. 26. Additional Requirements

Adds the following sections to the existing law:

Sec. 29. Expedited Action for Chemicals of Highest Concern

This section instructs EPA to act quickly act to manage risk from chemicals of highest concern.

Sec. 30. Children's Environmental Health Research Program.

This section requires EPA to establish within 90 days of enactment a research program focused on children's health, which would provide grants to independent researchers to support research that furthers understanding of children's vulnerability to industrial chemicals.

The section also requires EPA to establish within 90 days of enactment an advisory board with representation from other federal agencies with duties and expertise relevant to children's health and toxic chemicals, and from existing children's health centers.

The board would provide independent advice, expert consultation, and peer review upon request of the Administrator or Congress on the scientific and technical aspects of issues relating to the implementation of this Act with respect to protecting children's health and research.

Sec. 31. Reduction of Animal-Based Testing.

This section requires the Administrator to minimize the use of animals in testing of chemical substances or mixtures by encouraging the use of existing data, grouping of chemical substances for testing, formation of industry consortia to reduce redundancy, use of existing methods that eliminate or reduce the use of animals, and the development and validation of emerging methods and models. The Administrator would be required to establish an Interagency Science Advisory Board on Alternative Testing Methods and develop a strategic plan to promote alternative methods. This section will also allow a manufacturer or processor to request adaptation or waiver of animal testing requirements

Sec. 32. Safer Alternatives and Green Chemistry and Engineering.

This section seeks to support and encourage the development and use of safer alternatives to hazardous substances.

It requires, within 1 year of enactment, the establishment of a safer alternatives program to develop market and other incentives for safer alternatives. These include expedited review for new chemicals that claim to be safer for a given use than the conventional substance(s) and recognition for safer alternatives through special marketing designations, awards and rewards.

The section also calls on EPA to establish a green chemistry research network of at least 4 centers to support development and use of safer alternatives. EPA is to provide research grants to promote the development and use of safer alternatives, especially for priority hazardous chemicals for which alternatives do not presently exist.

Also, EPA is required to establish Green Chemistry Workforce Education and Training Program to facilitate the development of a workforce, including industrial and scientific workers, that produces safer alternatives to existing chemical substances.

Sec. 33. Cooperation with International Efforts.

This section requires EPA to cooperate with any international efforts undertaken to develop a common protocol or electronic database relating to chemical substances, or to develop safer alternatives for hazardous chemical substances.

Sec. 34. Reliable Information and Advice.

This section establishes procedures to ensure that the information that EPA uses to make safety determinations is accurate and reliable. Required procedures include random inspections laboratories conducting testing, auditing of data submissions, establishment of a mandatory registry of health and safety studies, EPA access to records of research, and funding source disclosure by researchers.

Sec. 35. Hot spots.

This section requires EPA to identify localities within the United States where the resident population is subject to disproportionate exposure to toxic chemical substances, and take action to reduce those exposures.

Sec. 36. Application of this act to federal agencies.

Requires other federal agencies to comply with the Act, and waives sovereign immunity as a defense. The President can grant exemptions in situations of paramount interest of the United States.

Sec. 37. Implementation of Stockholm Convention, the LRTAP POPs Protocol, and the Rotterdam Convention.

Provides for implementation by the United States of the provisions of Stockholm Convention, the LRTAP POPs Protocol, and the Rotterdam Convention that enter into force for

the United States. The manufacture, processing, distribution in commerce, use or disposal of any chemical subject to such provisions in a manner inconsistent with such obligations is prohibited. Also, provides a notice and comment process and authority for EPA for implementation and enforcement.