

Summary of Changes in Safe Chemicals Act of 2011 vs. 2010

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2010 bill	2011 bill
Sec. 3: Definitions	
Defines “adverse effect.”	Defers definition of this term to EPA.
Defines “aggregate exposure” to include certain non-TSCA uses of chemicals.	Clarifies that exposures arising from TSCA as well as non-TSCA uses are to be considered in assessing “aggregate exposures.”
Defines “bioaccumulative” based on EPA’s limited PBT criteria developed in 1999 for the New Chemicals Program.	Defines “bioaccumulative” to provide for consideration of monitoring and other types of data indicating actual or potential accumulation of a chemical in people or other organisms.
Defines “cumulative exposure” to include chemicals associated with “ <u>an adverse effect.</u> ”	Clarifies that cumulative exposures are from multiple chemicals that relate to “ <u>the same or similar</u> adverse effect.”
Defines “persistent” based on EPA’s limited PBT criteria developed in 1999 for the New Chemicals Program.	Defines “persistent” to provide for consideration of monitoring and other types of data indicating actual or potential persistence of a chemical in various environmental media.
Defines “reasonable certainty of no harm” to require assessment of both aggregate and cumulative exposures.	Establishes that the safety standard is to be based “solely on considerations of human health and the environment, including the health of vulnerable human populations.” Clarifies that cumulative exposures are to be considered where information is available that allows such consideration.
Sec. 4: Minimum data sets and testing of chemical substances and mixtures	
“The rule may provide for varied or tiered testing for different chemical substances, mixtures or categories of chemical substances and mixtures.”	“May” is changed to “shall” and minimum data sets (plural) are to be developed, to clarify that the minimum information required may differ among different types or classes of chemicals.
Minimum data sets [MDSs] are due within 18 months after prioritization for existing chemicals, and at the time of filing notification for new chemicals.	MDSs are due within the earlier of 18 months of assignment to a priority class (see Sec. 6 below) or 5 years of enactment, for existing chemicals; and at the time of filing notifications, for new chemicals.
All chemicals are subject to the requirement for submission of a minimum data set (MDS).	Chemicals of high concern and low concern (see Sec. 6 below) would not be subject to a mandatory MDS. All other chemicals would be subject to this requirement.

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Sec. 6: Prioritization, safety standard determination, and risk management	
<p>Chemicals are to be prioritized for safety determinations, based on production volume, use, hazard and exposure. [Categorization is provided for in Sec. 8 but is not tied to other actions.]</p>	<p>Chemicals are to be categorized as:</p> <ul style="list-style-type: none"> • Priority Class 1: Chemicals requiring immediate risk management (PBTs with potential for widespread exposure; list to include 20-30 such PBTs); • Priority Class 2: Chemicals requiring safety determinations (chemicals for which there is “more than a theoretical concern” as to whether the chemical would meet the safety standard); or • Priority Class 3: Chemicals requiring no immediate action (chemicals with inherent properties indicating no risk based on robust data).
<p>A priority list of not less than 300 chemicals is to be established as the basis for the order in which safety determinations are to be conducted. [Sec. 29, Expedited action on chemicals of highest concern, is limited to a single sentence: “The Administrator shall act quickly to manage risks from chemical substances that clearly pose the highest risks to human health or the environment.”]</p>	<ul style="list-style-type: none"> • Priority Class 1 chemicals would be subject to conditions EPA deems needed “to achieve the greatest practicable reductions in human or environmental exposure.” A safety determination for remaining sources of exposure would subsequently be conducted. • Priority Class 2 chemicals would be prioritized for safety determinations. The number of substances assigned to this class at a given time would be based on EPA’s capacity to expeditiously conduct safety determinations. • Priority Class 3 chemicals could be subject to a safety determination if new information is developed that calls into question or changes their categorization.
Burden of proof (BOP) is not separately delineated from duties of companies and EPA.	A clear statement that industry bears the legal BOP, and a separate clear statement of industry’s duty to provide information sufficient to determine safety, and EPA’s duty to make safety determinations, are provided.
In making safety determinations, EPA is to “consider” recommendations of the National Academy of Sciences (NAS).	EPA is to base determinations on the best science, which in turn must be based on “the recommendations of the National Academy of Sciences in the report entitled ‘Science and Decisions’.”

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Sec. 14: Disclosure of data	
Sharing of confidential business information (CBI) with state governments would be subject to any applicable agreements to maintain confidentiality.	Clarifies that CBI may only be shared where an agreement is in place to ensure the information is kept confidential.
	A new provision is added clarifying that nothing in this section limits EPA's authority to determine that particular information, previously considered entitled to CBI protection, is no longer so entitled.
Sec. 18: Preemption	
Actions taken under TSCA would not pre-empt State laws that are <u>more stringent than</u> TSCA.	Actions taken under TSCA do not affect the right of a State to adopt requirements or standards that are <u>different from or in addition to</u> those under TSCA, unless compliance with both the TSCA and the State requirement or standard is impossible.