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

Prepared by Richard A. Denison, Ph.D., Senior Scientist, Environmental Defense Fund

[Updated 5-9-11]

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 "an adverse effect."	Clarifies that cumulative exposures are from multiple chemicals that relate to "the same or similar 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 (in Sec. 6) 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 only "to the extent practicable" and where information is available that allows such consideration.
Sec. 4: Minimum data sets and testing of chemical substances	
"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. MDSs must provide sufficient "information necessary for the Administrator to conduct a screening-level risk-assessment." MDS development is to "encourage and facilitate the use of alternative testing methods and testing

2010 bill	*2011 bill*
	strategies to generate information quickly, at low cost, and without the use of animal-based testing, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening."
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.
Sec. 6: Prioritization, safety standard determination, and risk management	
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.]	Chemicals are to be categorized as: • 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).
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."]	• 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,

2010 bill	*2011 bill*
	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 is to be based on "the recommendations of the National Academy of Sciences in the report entitled 'Science and Decisions'." EPA's methodology for determinations is to be reviewed no less than every 5 years and revised "to reflect new scientific developments or understandings."
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.
All CBI claims would be subject to a five-year expiration.	EPA would be required to designate types of information for which the five-year term would not apply.
	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.
Generally applicable provisions	
EPA may prohibit production/use of a chemical in case of a violation of a requirement under the Act. *(appears in several sections)*	EPA may impose any condition listed under section 6(c) in case of a violation under the Act. *(replacement made in those same sections)*
Retains references throughout current TSCA to EPA's authority to require testing, reporting or regulation of mixtures.	Consolidates references to mixtures (in Sec. 26) and clarifies that "any action authorized or required to be taken by the Administrator or any other person under any provision of this Act with respect to a chemical substance is likewise also authorized or required with respect to a mixture, if the Administrator determines that such extension is reasonable and efficient."