MEMORANDUM

Date: June 11, 2013

Re: Key Differences Between Chemical Safety Improvement Act and Safe Chemicals Act

The Chemical Safety Improvement Act takes a dramatically different approach to reforming the federal Toxic Substances Control Act compared to the Safe Chemicals Act, as amended in 2012. This memorandum overviews some of the key differences between the Chemical Safety Improvement Act and the Safe Chemicals Act. Some of those differences include a weaker safety standard, heightened judicial review, lack of minimum data requirements, broad preemption language, lack of fee and cost-sharing provisions, and glaring lack of attention to vulnerable populations and biomonitoring data, among other things. The following comparison is limited by the fact that the Chemical Safety Improvement Act and the Safe Chemicals Act bear very little resemblance to each other. In particular, many of the critical reform provisions that appear in the Safe Chemicals Act, not to mention its predecessor, the Kid-Safe Chemicals Act, are completely missing from the Chemical Safety Improvement Act.

1. **Complete new framework for regulating chemicals compared to Safe Chemicals Act. [Sections 1-2]**

Unlike the Safe Chemicals Act, the Chemical Safety Improvement Act places far less emphasis on whether individual chemicals are safe and focuses very little on the need to protect vulnerable populations.

Title. The name of the bill, the "Chemical Safety Improvement Act," Section 1(a) (p. 1, line 6) [Short Title], emphasizes the issue of chemical safety generally without saying much about the importance of ensuring that individual chemicals are in fact safe. This is a departure from the Safe Chemicals Act, and certainly the Kid-Safe Chemicals Act introduced before that.

Findings. In contrast to the Safe Chemicals Act, the Chemical Safety Improvement Act's findings, policy, and intent section, Section 2 (p. 2), makes no reference to vulnerable populations; the extent to which chemicals burden our bodies as evidenced by biomonitoring studies; increased incidences of diseases and disorders linked to chemical exposures; or the fact that for years the public has been exposed to chemicals that have not been adequately reviewed and may harm human health and the environment. The Chemical Safety Improvement Act's findings suggest that "unmanaged risks," instead of individual chemicals themselves, "may pose a danger to human health and the environment." Section 2(b) (p. 3, line 7-9) [Findings]. The rest of the bill's findings focus on restoring public confidence in federal regulation of chemicals; the importance of chemicals to the economy; and the need for uniform regulation of such substances, among other things.

Missing Themes Throughout. Unlike the Safe Chemicals Act, the Chemical Safety Improvement Act makes no explicit reference in the entire bill to the following terms: "**workers**," "**pregnant**," "**children**," "**kids**," "**aggregate**" or "**cumulative**" exposure. The bill makes one reference to "**bioaccumulation**," "**persistence**," and "**biomonitoring**" in the context of listing the kind of information EPA may consider when developing guidelines for test data. Section 4 (p. 43-44, lines 3-9) [Chemical Assessment Framework, Types of Health & Environmental Data]. The only mention of "**vulnerable**" in the bill is where it mentions "vulnerability of exposed subpopulations" in the context of what kind of exposure information EPA has to consider when conducting a chemical safety assessment. Section 6 (p. 63, lines 3-4) [New Chemicals & Significant New Uses, Hazard, Use & Exposure Information]. (More on this point, the language here indicates that EPA is not being directed to take into account vulnerable populations when assessing hazards, at least not explicitly.)

2. **Safety standard substantially less rigorous than one in Safe Chemicals Act [Section 3, 6]**

The Chemical Safety Improvement Act's safety standard is defined as a "standard that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical." Section 3 (p. 9, lines 1-5). This is not a strictly health-based standard like the one used in the Safe Chemicals Act, which, as a matter of law, does not allow for cost-benefit analysis when developing a regulation. Rather, the unreasonable risk language — which is used in current law — has been read to require a cost-benefit analysis because the language implies there is such thing as reasonable or acceptable risk. See John S. Applegate, The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control, 91 Colum. L. Rev. 261 (1991).

Although the Chemical Safety Improvement Act says that EPA must evaluate whether a chemical meets the safety standard "based solely on considerations of risk to human health and the environment," Section 6 (p. 64-65), this does not change the fact that the safety standard, as defined, still involves some consideration of costs and benefits given the way "unreasonable risk" has been interpreted by the courts and certainly the Office of Management and Budget, which will review any proposed regulatory action by EPA under this bill.

Safe Chemicals Act by Comparison. In contrast, the Safe Chemicals Act would have required EPA to use a far more health-protective standard requiring a showing that there is "reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance," SCA Section 7 (p. 100-01), which means that for the safety determination, EPA would not have to consider the benefits of using a particular chemical.

Cumulative and Aggregate Exposures. Finally, note that no reference is made to aggregate or cumulative exposure when applying the safety standard under the Chemical Safety Improvement Act, which are both explicitly mentioned in the Safe Chemicals Act safety standard. Assessing aggregate exposure to chemicals is critical to ensuring public safety and

has been recommended by the National Academy of Sciences. In assessing the safety of a chemical it is necessary to consider exposure from different sources and through different exposure routes. It is also important to consider the cumulative effects from simultaneous exposure to different chemicals that affect the body through the same modes of action (MOA).

3. **Risk management requirements amount to pursuing least burdensome approach like what appears in current law**.
[Section 6]

If EPA determines that a chemical does not meet the safety standard, it must decide which risk-management measures it should take with respect to that chemical. Section 6 (p. 67-72). EPA may pursue a variety of restrictions, including, but not limited to, warnings, use restrictions, production restrictions, phase outs, and bans. Section 6 (p. 67-70). If EPA wants to phase out or ban a chemical, the agency has to conduct and present a careful cost-benefit analysis, including a discussion of technically and economically feasible alternatives, risks posed by each of those alternatives compared to the chemical being considered for regulation, and the economic and social costs and benefits of the proposed restriction compared to potential alternatives, among other things. Section 6 (p. 71-72). Therefore, although the CSIA removes the current law's least-burdensome restriction language, it reads it back into the bill with these requirements to pursue a phase out or ban.

Although the CSIA does not explicitly require the same analysis for other types of restrictions, in practice, it can be expected that EPA will have to perform similar analysis because of the unreasonable risk language in the safety standard. (Once again, this is certainly how the Office of Management and Budget will review any restriction proposed under the CSIA's risk-management provisions.)

In contrast, the Safe Chemicals Act's health-based safety standard does not allow for the same cost-benefit analysis and nothing in the risk-management section of the bill requires EPA to develop a detailed record, studying alternatives, economical and social costs, and the like.

4. **Exemptions allowed without EPA showing 'clear and convincing evidence.'**
[Section 6]

Like the Safe Chemicals Act, the Chemical Safety Improvement Act allows EPA to exempt chemicals from risk management under certain circumstances (e.g., national security interest and avoiding significant economic disruption). However, the Safe Chemicals Act would have required EPA to justify an exemption decision with "clear and convincing evidence," SCA Section 7 (p. 126), whereas the Chemical Safety Improvement Act only says EPA "may exempt the use of a chemical substance from any additional restrictions" if it meets these conditions, with nothing said about EPA's burden of proof to justify the exemption, making

them much more likely. Section 6 (p. 72, lines 4-24) [Safety Assessments & Determinations, Determination Chemical Substance Does Not Meet Safety Standard, Exemptions].

5. **No minimum information set requirements for new chemicals and prioritization**. **[Sections 4, 5]**

The Safe Chemicals Act had a specific section requiring chemical companies to submit minimum information sets necessary for EPA to evaluate new chemicals, new uses of chemicals, and to evaluate for prioritization, among other things. SCA Section 5 (p. 16) [Minimum Information Sets & Testing of Chemical Substances].

In contrast, the Chemical Safety Improvement Act does not require chemical manufacturers to submit to EPA minimum data sets for new chemicals and chemicals being assessed for safety. It only speaks generally about information EPA may need to evaluate chemicals. E.g., Section 4 (p. 29, lines 17-25 & p. 30, lines 1-4) [Chemical Assessment Framework, Development of New Test Data & Information]. Furthermore, the bill gives EPA the option of letting companies market new chemicals before it has enough information to decide if they are safe. Section 5 (p. 53, lines 11-15) [New Chemical and Significant New Uses, Additional Data and Information].

6. **Broad preemption language**.
[Section 15]

The Chemical Safety Improvement Act's section on preemption, Section 15 (p. 114-15), is both explicit and broad in effect and raises serious concerns on its impact of state laws such as California Proposition 65.

The bill states that no state may require additional development of test data or information on a chemical or chemical class for which companies have to submit similar information to EPA (e.g., for EPA chemical assessments). Section 15 (p. 114, lines 10-22) [Preemption]. Under laws such as Proposition 65, regulators have to develop data before listing a chemical or to determine certain safe harbor levels. The Chemical Safety Improvement Act's preemption language raises questions whether states could continue to carry out these steps to develop such data.

The bill goes on to say that no state may create a new, or continue to enforce an existing, restriction on the manufacture, processing, distribution, or use of a chemical after EPA completes a safety determination for that chemical. Section 15 (p. 114, lines 10-25 & 15, lines 1-9) [Preemption]. Further, states are prohibited from creating new restrictions on such chemicals' manufacture, processing, or distribution for chemicals EPA classifies as high- or low-priorities. Section 15 (p. 115, lines 10-24) [Preemption]. At the very least, this language is ambiguous as to whether states could still require companies to disclose to consumers information about chemicals and/or require that products carry warning labels since companies will be likely to argue that "distribution" covers product packaging decisions.

In contrast, the Safer Chemicals Act states that the bill would not affect the ability of individual states to impose additional safety requirements on chemicals, unless complying with state and federal law would be impossible. SCA Section 18 (p. 214).

7. **More protection of confidential business information than in Safer Chemicals Act**. **[Section 14]**

Chemical identity within health and safety data. In a striking departure from current law, the Chemical Safety Improvement Act would allow information elements—such as chemical identity—within health and safety studies and health and safety data submitted to the EPA in notices of substantial risk to be claimed confidential. Section 13 (p. 99-100).

Grandfathering of claims. The Chemical Safety Improvement Act would grandfather confidential business information (CBI) claims made before enactment, preventing EPA from requiring re-substantiation of such claims, Section 13 (p.113, lines 1-11) [Confidential Information, Applicability], unless the claims covered chemical identities or inventory information for chemicals classified by EPA as high-priority. Section 13 (p. 107, 22-25 lines & 108, lines 1-9) [Confidential Information, Redocumentation].

Access hurdles for Medical Personnel. The Chemical Safety Improvement Act also makes it harder than the Safe Chemicals Act for EPA to share the identity of confidential chemicals to medical personnel when that information is needed for treating patients or managing emergency situations. Section 13 (p. 103-106) [Confidential Information, Exceptions to Protection for Disclosure].

The Safe Chemicals Act would require EPA to disclose upon request confidential information to "public health or environmental health professionals or medical personnel" if EPA found disclosure to be in the public interest; found no conflict of interest or competitive interest on the part of the requester; and obtained a confidentiality agreement from the requester. SCA Section 14 (p. 184-85) [Disclosure of Data, Mandatory Exemptions].

The Chemical Safety Improvement Act makes it harder for public health officials to obtain confidential business information about chemicals from EPA. First, the bill refers to "health professional employed by a Federal or State agency or a treating physician or nurse" in a nonemergency situation rather than using broad language such as "public health officials" or "medical personnel" as the terms appear in the corresponding section of the Safe Chemicals Act. Section 13 (p. 104, lines 17-21) [Confidential Information, Exceptions to Protection for Disclosure]. For emergency situations, the Chemical Safety Improvement Act only allows disclosure treating physicians and nurses, with no mention made of healthcare professionals, regardless of whether they are employed by a federal or state agency. Section 13 (p. 105, lines 18-19) [Confidential Information, Exceptions to Protection for Disclosure].

Second, the Chemical Safety Improvement Act requires EPA to follow more detailed procedures before providing to these parties the confidential information. In nonemergency situations, the requester must first submit a "written statement of need" that contains a reasonable basis to suspect that the information is needed to diagnose or treat someone and that knowledge of the chemical identity will assist with such efforts. Section 13 (p. 104, lines 22-24 & p. 105, lines 1-9) [Confidential Information, Exceptions to Protection for Disclosure]. In emergencies, the bill requires this information to be provided as soon as practicable. Section 13 (p. 106, lines 12-15) [Confidential Information, Exceptions to Protection for Disclosure]. The Safe Chemicals Act did not spell out all of these procedures.

8. **Priority review no longer given to some of most troubling chemicals in use**. **[Section 4]**

The Safer Chemicals Act specifically focused on the need to make regulating persistent, bioaccumulative, and toxic (PBT) chemicals a top priority. In contrast, the Chemical Safety Improvement Act only mentions concerns about persistence and bioaccumulation in one place where it says EPA has the option of developing test guidelines for use in safety assessments. Section 4 (p. 44, lines 3-9) [Chemical Assessment Framework, Types of Health & Environmental Data & Information].

This same paragraph contains the only reference in the bill to "biomonitoring," where it says EPA may develop test guidelines on the "presence of the chemical substance or mixture in human blood, fluids, or tissue." Section 4 (p. 43-44, lines 3-9) [Chemical Assessment Framework, Types of Health & Environmental Data].

9. **Judges can still require "substantial evidence" from EPA to support rulemaking**. **[Section 16]**

The Chemical Safety Improvement Act uses the same judicial standard of review that appears in Toxic Substances Control Act, allowing courts to "hold as unlawful and set aside [a] rule if the court finds that the rule is not supported by substantial evidence." Section 16 (p. 122, lines 15-19) [Judicial Review]. As the 5th Circuit noted in Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (1991) (ruling prevented EPA from banning asbestos under TSCA), this standard of review is considered more rigorous and invites considerably more general judicial review than the standard of review used to evaluate rules under other environmental statutes, which only require an agency to show that it acted reasonably. The Safe Chemicals Act would have reformed the Toxic Substances Control Act to replace the substantial evidence standard with a reasonableness standard, SCA Section 19 (p. 214-16).

Further, the Chemical Safety Improvement Act states that safety determinations by the EPA are considered "final agency action," "subject to judicial review." Section 6 (p. 73, lines 3-4) [Safety Assessments & Determinations, Safety Determination, Final Agency Action]. In contrast, the Safe Chemicals Act would have made ineligible for judicial review any safety determination by the EPA, SCA Section 7 (p. 103).

10. **Opportunities for companies to delay review process and absence of clear deadlines**.

Deadlines. Language throughout the Chemical Safety Improvement Act provides no clear deadlines for EPA to complete safety reviews of chemicals, including, but not limited to, EPA's directive to prioritize chemicals and make safety determinations.

The bill directs EPA to "make every effort to complete the prioritization of all active substances **in a timely manner**," Section 4 (p. 18, lines 22-25) [Chemical Assessment Framework, Timely Completion of Prioritization Process] (emphasis added). It also says EPA only has to publish a list of chemicals being considered for prioritization "**from time to time**." Section 4 (p. 19, lines 21-23) [Chemical Assessment Framework, Timely Completion of Prioritization Process] (emphasis added). The bill also gives EPA the opportunity to delay with respect to meeting deadlines for safety assessments and determinations. Section 6 (p. 59, lines 16-24) [Safety Assessments & Determinations] ("deadlines . . . may vary among chemical substances to grant the Administrator **flexibility**; and . . . shall allow for r**easonable extensions** after an adequate public justification") (emphasis added). Moreover, it directs EPA to make safety determinations "**as soon as possible**." Section 6 (p. 64, lines 5-11) [Safety Assessments & Determinations, Safety Determination] (emphasis added). Missing are the hard deadlines that appear in the Safe Chemicals Act. E.g., SCA Section 7 (p. 80-81) (EPA must categorize a first batch of chemicals no later than 180 days after issuing categorization and prioritization regulations).

Additional Opportunities for Delay. The bill gives chemical companies a number of opportunities to delay EPA's review of chemicals, as well. For example, if EPA determines that additional test information is needed to make a safety assessment, the agency is directed to "provide an opportunity for interested persons to submit the additional information," but gives no deadlines for that information to be developed. Section 6 (p. 63, lines 9-13) [Safety Assessments & Determinations, Additional Test Information]. In other words, companies would have the option of taking their time to produce this information if they choose to do so, thus delaying the review process.

11. **Lack of fees and cost-sharing provisions**.

Another significant difference between the Chemical Safety Improvement Act and the Safe Chemicals Act is with respect to giving EPA the ability to require fees from chemical manufacturers to help share the cost of reviewing chemicals for safety and managing associated risks. The Safe Chemicals Act would allow EPA to require by rule "payment of a reasonable fee from any person required to submit data to defray the cost" of administering provisions in the bill. SCA Section 23 (p. 221). In contrast, the Chemical Safety Improvement Act has nothing to say about fees or cost-sharing, making it more difficult for EPA to obtain and develop the test data needed to evaluate the safety of individual chemicals.

12. **Lack of authority to regulate new nanomaterials**.

The Safe Chemicals would give the EPA authority to regulate nanomaterials as separate chemical substances by allowing the agency to consider a variant of a chemical substance as a new chemical substance. SCA Section 4 (p. 9). It also would allow the EPA by order or rule to establish the physical, chemical, or biological characteristics, other than molecular identity, that may significantly affect the risks posed by a chemical substance. SCA Section 4 (p. 13).

In contrast, the Chemical Safety Improvement Act fails to update the definition of "chemical substance" that is contained in current law, which limits the differentiation of chemical substances to particular molecular identities.

13. **No sections on hot spots, green chemistry, or children's health research; little emphasis on information sharing with international partners**.

The Safe Chemicals Act had specific sections addressing "hot spots," or locations with disproportionately higher exposure levels to chemicals, SCA Section 34 (p. 238); creating a children's environmental health research program, SCA Section 29 (p. 224); spurring the development of safer alternatives through green chemistry, SCA Section 31 (p. 234); and encouraging international cooperation to manage and regulate chemical risks, SCA Section 32 (p. 237).

The Chemical Safety Improvement Act has none of these sections. The only discussion of safer alternatives or safe chemistry appears briefly in two places, see Section 2 (p. 4, lines 10-12) [Findings] ("innovation in the development of new chemical substances, especially safer chemical substances, should be encouraged . . . ."); Section 2 (p. 7, lines 1-5) [Intent] ("implement this Act to protect the health of the people . . . in such a manner as not to unduly impede commerce or create unnecessary economic barriers . . . to innovation, including safer chemistry.").