COMPARISON OF THE AMERICAN CHEMISTRY COUNCIL'S "10 PRINCIPLES FOR MODERNIZING TSCA" AND THE SAFE CHEMICALS ACT OF 2013

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ACC PRINCIPLES FOR MODERNIZING TSCA	SAFE CHEMICALS ACT OF 2013 (SCA)[1]
1. Chemicals should be safe for their intended use.	• The safety determination is made on a chemical use basis: EPA is to determine whether a "chemical substance meets the safety standard for all current uses and under conditions currently used" or "can only meet the safety standard for a subset of all current uses or only under conditions beyond those currently used" [Section 6(d)(5)(B) and (C)]
• Ensuring chemical safety is a shared responsibility of industry and EPA. • Industry should have the responsibility for providing sufficient information for EPA to make timely decisions about safety. • EPA should have the responsibility for making safe use determinations for high priority chemicals, focusing on their most significant uses and exposures.	• The sharing of responsibility is explicit and the duties of each party match those specified by ACC: "[i]t shall be the duty of the manufacturer or processor of a chemical substance to provide sufficient information for the Administrator to determine whether the chemical substance meets the safety standard;" and "it shall be the duty of the Administrator to determine whether a chemical substance meets the safety standard." [Section 6(d)(1)(B)(ii)] • Safety determinations are to be conducted first on all chemicals identified as priority class 1. [Section 6(d)(4)(A)]
• Safe use determinations should integrate hazard, use, and exposure information, and incorporate appropriate safety factors.	• Chemicals to undergo safety standard determinations are to be selected "based on a screening of available use, hazard, and exposure information." [Sections 5(b)(2)(D)(iii)(III) and 6(b)(3)(B)(iii)] • Such chemicals are to be prioritized for safety determinations based on consideration of both hazard and exposure. [Section 6(b)(4)(B)] • The minimum information set required for safety determinations is to include information on "toxicological properties, environmental and biological fate and behavior, exposure, and use of a chemical substance." [Section 4(a)(1)(B)(iii)] • EPA is to base safety determinations on "the recommendations of the National Academy of Sciences in the report entitled 'Science and Decisions'." [Section 6(d)(2)(D)(ii)] That NAS report includes extensive discussion of the need to use appropriate safety factors (see especially Chapter 6).
• Consideration of the benefits of chemicals being evaluated, the cost of methods to control their risks, and the benefits and costs of alternatives should be part of EPA's risk management decision-making, but should not be part of its safe use determinations.	• EPA is to base safety determinations "solely on considerations of human health and the environment." [Section 6(d)(2)(B)(i)] • Risk management decisions are to account for benefits and costs in several ways: ▪ EPA may allow more time for implementation of risk management measures where compelling technological needs (e.g., lack of availability of an alternative) or factors outside of the control of a company require a longer period to comply. [Sections 6(d)(5)(D)(iii), 6(d)(5)(F)(ii), 6(e)(2)(C)] ▪ Companies may request and EPA may grant renewable

[1] The section references are to the Toxic Substances Control Act as amended by the Safe Chemicals Act of 2013.

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	exemptions from risk management restrictions for continued use of a chemical where: ▪ it "is in the paramount interest of national security; ▪ the lack of availability of the chemical substance would cause significant disruption in the national economy; or ▪ the use for which the exemption is sought is a critical or essential use for which: ▪ no feasible safer alternative for the specified use of the chemical substance is available; or ▪ the specified use of the chemical substance, as compared to all available alternatives, provides a substantial net benefit to human health, the environment, or public safety." [Section 6(h)(2)(B)]
• Other agencies, such as FDA and CPSC, should continue to make safety decisions for products within their own jurisdictions.	• For chemicals that (a) have some uses that fall under TSCA and other uses that fall under another agency's jurisdiction, and (b) fail to meet the safety standard without additional conditions, EPA can only act to restrict the chemical if it has notified the other agency of actions needed to be taken, and that agency fails to act or fails to respond. *[Section 9(a)]* • Current TSCA already provides EPA with risk management authorities that extend to "articles," and hence overlap with authorities granted under different laws to CPSC; these authorities are carried over into SCA. [Section 6(a) of current TSCA; Section 6(f) of SCA]
2. EPA should systematically prioritize chemicals for purposes of safe use determinations.	• Revisions to SCA institute a highly systematic procedure for categorizing chemicals to determine which need safety determinations, and a second highly systematic procedure for prioritizing those substances to be subject to safety determinations. [Sections 6(b)(3) and (4)]
• Government and industry resources should be focused on chemicals of highest concern.	• As a first step, EPA is to identify chemicals of very low concern and set them aside. [Section 6(b)(3)(B)(ii)] • Chemicals to be subject to safety determinations are to be prioritized so that those EPA deems of highest concern based on available information are first in line. [Section 6(b)(4)]
• The priorities should reflect considerations such as the volume of a chemical in commerce; its uses, including whether it is formulated in products for children; its detection in biomonitoring programs; its persistent or bioaccumulative properties; and the adequacy of available information.	• Chemicals first to be evaluated are identified based primarily on their production volume, with EPA having the ability also to include chemicals that "are used or released into the environment in a manner that the Administrator determines warrants early evaluation." [Section 6(a)(3)(B)(i)] • Chemicals assigned the highest priority are those with "relatively greater hazard potential and for which there is evidence of more significant or widespread exposure." [Section 6(b)(4)(C)(i)(II)] • Chemicals with inadequate information are to be identified at the first step and subject to information requirements. [Section 6(b)(3)(B)(iv)]
3. EPA should act expeditiously and efficiently in making safe use determinations.	• Revisions to SCA balance the need for expeditious review with recognition of the expected limited resources available to EPA. In deciding how many safety determinations it can conduct in a given time period, EPA is to "seek to balance considerations relating to: ▪ the number of chemical substances for which safety standard determinations need to be conducted; ▪ the resources available to the Administrator for conducting

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	safety standard determinations; and ▪ the deadlines for completion of safety standard determinations." [Section 6(b)(4)(C)(i)(IV]
• Since a chemical may have a variety of uses, resulting in different exposure potentials, EPA should consider the various uses and focus on those resulting in the most significant exposures.	• Chemicals to undergo safety standard determinations are to be selected "based on a screening of available use, hazard, and exposure information." [Section 6(b)(3)(B)(iii)] • Such chemicals are to be prioritized for safety determinations based on consideration of both hazard and exposure. [Section 6(b)(4)(B)] • Chemicals assigned the highest priority are those with "relatively greater hazard potential and for which there is evidence of more significant or widespread exposure." [Section 6(b)(4)(C)(i)(II)] • The minimum information set required for safety determinations is to include information on use and exposure as well as toxicological properties and environmental and biological fate and behavior. [Section 4(a)(1)(B)(iii)] • For chemicals identified as substances of very high concern, EPA is to: ▪ publish an identification and assessment of the known uses of, and exposures to, the chemical. [Section 6(e)(1)(B)] ▪ based on this assessment, impose restrictions and other conditions on those uses that will "achieve the maximum practicable reduction in human or environmental exposure to the chemical substance." [Section 6(e)(2)(A)]
• EPA should complete safe use determinations within set timeframes.	• EPA is to complete safety determinations for all chemicals identified as highest priority within 5 years. [Section 6(d)(4)]
4. Companies that manufacture, import, process, distribute, or use chemicals should be required to provide EPA with relevant information to the extent necessary for EPA to make safe use determinations.	• Revisions to SCA provide a carefully phased and tiered process for the development and consideration of information, starting with information already available to EPA, then information already available to companies, and finally development of new information necessary for EPA to make safety determinations.
• Companies throughout the chain of commerce should be responsible for providing necessary hazard, use, and exposure information.	• EPA is authorized to require "any person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance, or a mixture or article containing the chemical substance" to report hazard, use and exposure information EPA needs to administer the Act. [Section 8(g)(1)(A)] • Periodic reporting of chemical hazard, use and exposure information is to be required of chemical manufacturers [Section 8(c)] and chemical processors [Section 8(e)].
• EPA should be authorized to require companies, as appropriate, to generate relevant new data and information to the extent reasonably necessary to make safe use determinations without having to prove risk as a prerequisite or engaging in protracted rulemaking.	• EPA is authorized to require companies to: ▪ generate a "minimum information set to include sufficient information for the Administrator to conduct a screening-level risk assessment of the chemical." [Section 4(a)(1)(B)(iii)] ▪ conduct testing "as appropriate for making any determination or carrying out any provision of this Act." [Section 4(b)(1)(A)] • EPA may require the development of new information by order (which does not require full rulemaking), without having to first prove risk. [Section 4(b)(1)(A)]
• Testing of chemicals should progress to more complex and	• In establishing minimum information sets, EPA must "provide

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expensive tests through a tiered approach as needed to identify hazards and exposures of specific concern.	for varied or tiered information to be provided for different chemical substances" [Section 4(a)(1)(B)(i)] • EPA may require a company "to submit preliminary information" prior to proceeding to develop fuller information. [Section 4(c)(2)(B)] • In requiring testing and timing of submission of test data, EPA must consider: ▪ the relative costs of the various test protocols and methodologies that may be required; and ▪ the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required. [Section 4(c)(2)(A)]
• To minimize animal testing, existing data should be considered prior to new testing, and validated alternatives to animal testing should be used wherever feasible.	• EPA's testing requirements must "accommodate the use of alternative testing methods and testing strategies to generate information quickly, at low cost, and with reduced use of animal-based testing, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening, to the extent such methods and strategies would yield information of equivalent quality and reliability." [Section 4(a)(B)(v)] • EPA is required to take action to minimize the use of animals in testing including by relying on validated non-animal testing methods and information sources. *[Section 30]* • See provisions cited immediately below regarding use of existing information.
• Existing data and information should be leveraged in EPA's safe use determinations, including data and information from other mandatory and voluntary programs such as REACH and the U.S. High Production Volume challenge.	• In making categorization and prioritization decisions, EPA is to take into account: ▪ "information … that is available to the Administrator at the time the decisions are made; [Sections 5(b)(2)(B) and 6(b)(2)(A)] ▪ information identified through an "active search" by EPA of "information sources that are publicly available or otherwise accessible to" EPA; [Section 6(b)(2)(A)(iv)] ▪ for new chemicals: ▪ "information submitted to a governmental body in another jurisdiction, to the extent that the information is accessible to the Administrator;" [Section 5(b)(2)(B)(ii)] ▪ Information derived from validated estimation models or from extrapolation from closely related chemicals; [Section 5(b)(2)(B)(iii) and (iv)] ▪ decisions made in other jurisdictions; [Section 6(b)(1)(C)] • In making safety determinations, EPA is to take into account: ▪ "information … that is already available to the Administrator at the time the determination is to be made; [Section 6(d)(3)(A)(i)] ▪ information identified through an "active search" by EPA of "information sources that are publicly available or otherwise accessible to" EPA; [Section 6(d)(3)(A)(i)(IV)] ▪ decisions made in other jurisdictions; [Section 6(d)(3)(A)(iv)(II)] ▪ information voluntarily submitted by manufacturers and processors [Sections 6(b)(2)(B) and 6(d)(3)(A)(i)(III)] • Companies may apply for and EPA may grant exemptions from

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	testing requirements where information on an equivalent chemical is available or under development or where the required information would be duplicative of information that has already been submitted to EPA or is under development. [Section 4(d)]
5. Potential risks faced by children should be an important factor in safe use determinations.	• SCA emphasizes the need to ensure protection of children in making safety determinations for chemicals.
• Safe use determinations should consider the effects of a chemical on children and their exposure to the chemical.	• Processors are required to report on the presence of their chemicals in "any products intended for use by children aged 14 years or younger." [Section 8(e)(2)(C)(v)] • The safety standard is to explicitly account for risks to "vulnerable populations" [Section 6(d)(2)(B)(i)], which is defined to include infants, children, adolescents and pregnant women. *[Section 3(25)]*
• Safe use determinations should consider whether an extra margin of safety is needed to protect children.	• In addition to the mandate to protect vulnerable populations just noted, EPA is to base safety determinations on "the recommendations of the National Academy of Sciences in the report entitled 'Science and Decisions'." [Section 6(d)(2)(D)(ii)] That NAS report includes extensive discussion of the need to use appropriate safety factors, including those needed to account for differential vulnerability due to human variability and age differences (see especially Chapter 6). • The safety standard is to provide "a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance." [Section 6(d)(2)(B)(ii)(II)] This standard, derived from the Food Quality Protection Act, has generally been implemented by EPA using an additional safety factor to ensure protection of children.
6. EPA should be empowered to impose a range of controls to ensure that chemicals are safe for their intended use.	• Authority to impose risk management controls is provided to EPA. [Section 6(f)]
• The controls could range from actions such as labeling, handling instructions, exposure limits and engineering controls to use restrictions and product bans.	• Authority to impose these specific risk management controls is provided to EPA. [Section 6(f)]
• The controls should be appropriate for managing the risk, taking into account alternatives, benefits, costs, and uncertainty.	• Risk management decisions are to account for benefits and costs in several ways: ▪ EPA may allow more time for implementation of risk management measures where compelling technological needs (e.g., lack of availability of an alternative) or factors outside of the control of a company require a longer period to comply. [Sections 6(d)(5)(D)(iii), 6(d)(5)(F)(ii), 6(e)(2)(C)] ▪ Companies may request and EPA may grant renewable exemptions from risk management restrictions for continued use of a chemical where: ▪ it "is in the paramount interest of national security; ▪ the lack of availability of the chemical substance would cause significant disruption in the national economy; or ▪ the use for which the exemption is sought is a critical or essential use for which: ▪ no feasible safer alternative for the specified use of the chemical substance is available; or ▪ the specified use of the chemical substance, as compared to all available alternatives, provides a substantial net benefit to human health, the environment, or public safety." [Section 6(h)(2)(B)]

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7. Companies and EPA should work together to enhance public access to chemical health and safety information.	• SCA contains a number of provisions to enhance public access to chemical information.
• EPA should make chemical hazard, use, and exposure information available to the public in electronic databases.	• EPA is required to make decisions made by EPA or information it receives available to the public via an Internet-accessible database. [Section 8(i)]
• Other governments should have access to confidential information submitted under TSCA, subject to appropriate and reliable protections.	• State and tribal governments are to be provided, upon request, with access to confidential business information (CBI) received by EPA, subject to requirements that they maintain the confidentiality of the information. [Section 14(a)(2)(A)(iv)] • NOTE: A similar provision that would have provided access to foreign governments under certain conditions was removed from SCA after it was objected to by some industry representatives.
• Companies claiming confidentiality in information submittals should have to justify those claims on a periodic basis.	• Except for information deemed always eligible or never eligible for CBI protection [Sections 14(b)(1) and (3), respectively], each CBI claim must include a justification for the claim. [Section 14(c)(2)(B)(i)] • Such CBI claims are eligible for renewal if they are reasserted and rejustified before the expiration of the period of time for which they were approved. [Sections 14(b)(2)(B)(iii)(II) and 14(c)(1)(B)(iv)(II)]
• Reasonable protections for confidential as well as proprietary information should be provided.	• All of the basic protections for CBI provided under current TSCA are retained in SCA. Changes from current TSCA are reasonable and have substantial industry support. • The types of information typically claimed as CBI and warranting such protection are specifically delineated as "always eligible for protection." [Section 14(b)(1)] • Chemical identities for new chemicals are generally eligible for CBI protection for a period of time after they enter the market, with some exceptions. This eligibility extends even to the identities of chemicals that are the subject of health and safety studies, which under current TSCA are ineligible for CBI protection. [Section 14(b)(2)(B)] • Sunset dates apply to most CBI claims, with exceptions for types of information deemed always eligible for protection and other information elements EPA determines "warrant protection for an indefinite period of time." As previously noted, claims subject to sunsetting are renewable if reasserted and eligibility criteria are still met. [Sections 14(b)(2)(B)(iii) and 14(c)(1)(B)(iv)] • Criminal penalties for disclosure of CBI are eliminated, but civil penalties remain. Civil penalties also apply to making knowingly false CBI claims. [Section 14(d)]
8. EPA should rely on scientifically valid data and information, regardless of its source, including data and information reflecting modern advances in science and technology.	• SCA in general relies on information developed and submitted by industry as well as by other parties or otherwise available, and applies the same criteria to data from any source in judging its quality and reliability. • EPA is to periodically review the standards it prescribes for the use in the development of information. [Section 4(c)(3)(C)] • EPA is to periodically review the methodology it uses to conduct safety determinations and "revise the methodology to reflect new scientific developments or understandings." [Section 6(d)(2)(D)(iii)]

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	• EPA may redetermine the safety of a chemical "if significant changes have occurred in the methodologies used in the initial safety standard determination such that a redetermination using the newer methodologies would provide a significantly improved determination of the safety of the chemical substance." [Section 6(d)(5)(E)(ii)] • EPA is required to take action to encourage and facilitate the use of validated non-animal testing methods and information sources. *[Section 30]*
• EPA should establish transparent and scientifically sound criteria for evaluating all of the information on which it makes decisions to ensure that it is valid, using a framework that addresses the strengths and limitations of the study design, the reliability of the test methods, and the quality of the data.	• The rule EPA is to issue to establish minimum information sets is to specify "information quality and reliability requirements." [Section 4(a)(1)(B)(iv)] • The rules EPA is to issue to establish how it will categorize new chemicals and categorize and prioritize existing chemicals are to "describe criteria and factors the Administrator will use to assess weight of evidence and the quality and reliability of information." [Sections 5(b)(2)(A)(ii) and 6(b)(1)(D)] • EPA is to consider the quality and reliability of available information in deciding whether to categorize a new or existing chemical as one with insufficient information. [Sections 5(b)(2)(D)(iv)(I) and 6(b)(3)(B)(iv)(I)] • EPA is to consider the quality and reliability of information derived from alternative methods in determining its adequacy for meeting minimum information requirements. [Section 4(a)(1)(B)(v)]
• EPA should encourage use of good laboratory practices, peer review, standardized protocols, and other methods to ensure scientific quality.	• Test rules or orders issued by EPA are to specify the standards to be used to develop the information. [Section 4(c)(1)(B)] • EPA is generally to establish standards and methodologies for the development of health and environmental information. [Section 4(c)(3)(A) and (B)] • Persons submitting information to EPA are to certify that the information is accurate and reliable. [Sections 4(g), 5(i), 6(l) and 8(m)] • SCA retains sections of TSCA that address data reliability, including Sections 10 and 27. • SCA adds a new section designed specifically to "ensure data reliability." [Section 33]
9. EPA should have the staff, resources, and regulatory tools it needs to ensure the safety of chemicals.	• EPA has authority to "require the payment of a reasonable fee from any person required to submit data to defray the cost of administering this Act." *[Section 26(b)]*
• EPA's budget for TSCA activities should be commensurate with its chemical management responsibilities.	• There is widespread consensus on this point. This issue is a matter for appropriations, but the bill provides that "There are authorized to be appropriated to the Administrator to carry out this Act such sums as may be necessary." *[Section 38]*
10. A modernized TSCA should encourage technological innovation and a globally competitive industry in the United States.	• Section 5, addressing new chemicals, strikes a balance between, on the one hand, encouraging innovation and allowing chemicals on the market quickly and with relatively little information and pre-market review, but on the other hand, also ensuring sufficient review before market entry to screen out chemicals of very high concern and more substantial review and action to be undertaken relatively soon after market entry (see provisions cited below). • SCA includes several findings that speak directly to innovation and global competitiveness. *[Section 2(a)(2), (10) and (11)]*

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	• SCA includes a policy statement that speaks to the importance innovation. *[Section 2(b)(2)]* • SCA includes a section to ensure cooperation of the Federal government with international efforts aimed at facilitating the sharing of chemical information and the development of safer alternatives. *[Section 32]*
• A new chemical management system should preserve and enhance the jobs and innovative products and technologies contributed by the business of American chemistry. • Implementation of TSCA should encourage product and technology innovation by providing industry certainty about the use of chemicals.	• SCA includes a section devoted specifically to promoting green chemistry and encouraging and facilitating the "development, marketing and use" of chemicals and chemical products that are safer alternatives to existing substances and products. *[Section 31]* • Key provisions of Section 5, addressing new chemicals, include the following: ▪ EPA must reach categorization decisions on new chemicals within 90 days, the same period provided for new chemical reviews under current TSCA. [Section 5(b)(2)(C)] ▪ New chemicals not found by EPA to be likely to meet the safety standard may nonetheless enter the market in order to serve critical or essential uses. [Section 5(b)(1)(C)(ii)] ▪ In categorizing new chemicals, EPA is to rely principally on available information and information estimated and inferred from models or closely related chemicals. [Section 5(2)(B)(ii)] ▪ New chemicals EPA designates to undergo safety determinations may enter the market upon the filing of a notice of commencement, and are added to the current or next batch of existing chemicals for prioritization. [Section 5(b)(2)(D)(iii)(IV)] ▪ Exemptions from some or all of the requirements otherwise applicable to new chemicals are provided for intrinsically safe chemicals [Section 5(h)(1)], chemicals produced for test marketing purposes [Section 5(h)(2)], R&D chemicals [Section 5(h)(4)] and reaction intermediates [Section 5(h)(5)]. • As noted earlier, chemical identities for new chemicals are generally eligible for CBI protection for a period of time after they enter the market, with some exceptions. This eligibility extends even to the identities of chemicals that are the subject of health and safety studies, which under current TSCA are ineligible for CBI protection. [Section 14(b)(2)(B)]