

MEMORANDUM

Date: March 11, 2014

Re: EWG's Critique of "Chemicals in Commerce Act" Discussion Draft

Environmental Working Group (EWG) appreciates the work that went into drafting the Chemicals in Commerce Act (CICA) discussion draft and we fully agree that the federal Toxic Substances Control Act (TSCA) is broken and in dire need of reform.

EWG has long advocated reform of TSCA, as the law has failed to protect consumers that are exposed to thousands of chemicals in their everyday lives. However, EWG has serious concerns with this discussion draft and strongly opposes it as a path for reform. Like the Chemical Safety Improvement Act (S.1009), the CICA would result in less protection for public health and the environment than current law. The CICA would not only maintain many of the key deficiencies found in TSCA, it also would drastically curtail the ability of states to take steps to ensure that chemicals are safe, particularly for vulnerable populations.

The following provides an in-depth look at the CICA's critical flaws:

1) Lack of emphasis on ensuring that chemicals are safe, compared to protecting commerce.

From the very beginning, the CICA makes it clear that its focus is on protecting commerce first and ensuring that chemicals are safe, especially for children and other vulnerable populations, second.

Title: The very title, "Chemicals in Commerce Act," reveals that the draft's principal concern is protecting chemicals for commerce rather than protecting public health and the environment. Section 1 (p. 1, lines 5-6).

Findings: The CICA's findings only suggest that "unmanaged risks," instead of individual chemicals themselves, "may pose a danger to human health and the environment." Section 2 (p. 3, lines 3-5). Although the findings section briefly states that "chemicals in commerce should be safe for their intended use," and vaguely mentions "reduc[ing] risk," the section 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 for safety. Section 2 (p. 3, lines 1-13). Instead, the findings largely focus on the need to restore public confidence in the regulation of chemicals and the importance of developing new chemicals to "improve[] products, stimulate the economy, create jobs, and protect interstate commerce." Section 2 (p. 3, lines 6-7, 10-13).

Purpose: The CICA's solely stated purpose is "to promote *uniform protections* to human health and the environment through regulating chemical substances in commerce while *minimizing*

undue burdens on commerce.” Section 2 (p. 3, lines 14-17) (emphasis added). Therefore, the purpose of the CICA appears to be preempting state laws regulating chemicals, more so than ensuring the safety of chemicals.

Scant attention to vulnerable populations: The CICA uses the term “potentially exposed subpopulations” instead of “vulnerable populations” in the definition section. Section 3 (p. 5, lines 5-14). The definition of this term states that such subpopulations “where appropriate *may* include infants, children, pregnant women, workers and the elderly.” Section 3 (p. 5, lines 12-14) (emphasis added). Noticeably absent from this definition are environmental justice and fence-line communities, whose residents often are exposed to toxic chemicals through the air, land, and water surrounding chemical plants.

As for consideration of these subpopulations, the CICA states that EPA would be required to “analyze exposure to the chemical substance for the specific uses that are significant to the risk of harm and subsets of exposure (including information on potentially exposed subpopulations)” when making a safety determination. Section 6 (p. 38, lines 4-7). However, the CICA contains no other mention of vulnerable populations, or explicit mention of potentially exposed subpopulations, making it woefully inadequate to ensure protections for such populations. For example, consideration of vulnerable populations is not listed as an explicit factor for EPA to consider when prioritizing chemicals for review. Further, the CICA contains no references to aggregate and cumulative exposure, bioaccumulation, or persistence — key issues for pregnant women, children, and other vulnerable populations that must be addressed in any TSCA reform measure.

2) Serious limits on the science EPA may review and employ when evaluating chemicals.

The CICA’s requirements with respect to best available science and information quality may have the effect of significantly limiting the data and studies EPA may use to evaluate the safety of chemicals and regulate any risks they may pose. They also may result in lengthy challenges by the chemical industry over EPA’s reliance on certain information to justify restrictions on chemicals needed to protect public health and the environment.

Specifically, the CICA requires EPA to use “best available science” when making a decision under sections 4 (testing), 5 (new chemicals and significant new uses), and 6 (existing chemicals). Section 22 (p. 90, lines 8-11). The bill states five requirements for “best available science,” several of which may exclude information relevant to evaluating chemical safety. Section 3 (p. 4, lines 5-19).

For example, one requirement specifies that the science should “appl[y] scientifically valid, relevant, publicly available information.” Section 3 (p. 4, lines 12-13). In many cases, the science applicable to evaluating the safety of a chemical may be limited to industry studies or internal company studies, which often are not publicly available, and therefore, may fall outside the CICA’s definition of best available science.

Another CICA requirement states the science must apply certain information quality criteria established by EPA, which must ensure that science is “produced according to validated methods or processes” where possible, and “to the extent practicable, require the use of good laboratory practices, scientifically reliable test methods, standardized test protocols, consistent data evaluating procedures,” among other criteria. Section 22 (p. 89, line 1 – p. 90, line 7). These requirements could result in the exclusion of highly relevant and informative data and studies generated by academic institutions, depending on how these terms are interpreted.

The CICA’s requirements with respect to best available science and information quality must be clarified to avoid unnecessary confusion and to ensure that EPA has the authority to consider all relevant and applicable information when assessing chemicals.

3) No requirements for minimum information sets, among related considerations.

Perpetuating a significant weakness in current law, the CICA would not require companies to submit minimum data sets to the EPA for existing or new chemicals. Companies must be required to submit minimum information sets to EPA so that the agency can make a sound decision about a chemical’s potential to harm human health and the environment based on adequate information. Minimum data set requirements would save time for EPA and companies by reducing the data EPA would have to request through a test rule, consent agreement, or order.

The CICA would increase EPA’s authority to require manufacturers and processors to develop test data for chemicals through a test order as opposed to a rulemaking, Section 4 (p. 7, line 5). However, to exercise such authority EPA would have to explain why “good cause” exists for issuing an order as opposed initiating a rulemaking or negotiating and entering into a consent agreement. Section 4 (p. 9, line 24 – p. 10, line 3). For the explanation of good cause to be sufficient, EPA would have to address a host of different considerations. Such a showing could unnecessarily hinder EPA’s ability to fill critical data gaps about chemicals, including those that could be better addressed by requiring companies to submit minimum data sets. The good cause requirement also could force EPA to utilize the more resource-intensive rulemaking or consent agreement process, thus eroding the benefit of being able to employ test orders.

The CICA also limits EPA’s ability to follow up with manufacturers or processors with additional requests for test data to be developed. Section 4 (p. 14, lines 17-23).

Finally, language throughout the CICA greatly limits EPA’s ability to require animal testing to evaluate the safety of chemicals. EWG strongly supports the development of reliable alternatives to animal testing and reduction in animal testing when possible. However, despite progress made in recent years, current science has yet to provide validated alternatives that can produce the same information as animal tests. EPA’s ability to deliver meaningful protection to public health and the environment should not be halted until these alternative methods are developed. A better approach to this issue would be to incentivize the development of these alternatives.

4) New chemicals

The CICA would perpetuate a weak system of review for new chemicals that fails to provide EPA with the information needed to effectively assess the safety of chemicals and would require EPA to apply a safety standard that would inadequately protect public health. As discussed above, chemical companies would not be required to submit a minimum data set to EPA when notifying the agency of their intent to produce a new chemical, or to begin production of a chemical for a significant new use. Further, utilizing whatever data EPA is able to obtain, the agency could only evaluate the safety of a new chemical under its “intended conditions of use.” Section 5 (p. 23, lines 5-6). The standard for determining the safety of a new chemical remains the burdensome “unreasonable risk” standard addressed in greater detail in Section 6 of this memo. Section 5 (p. 23, lines 7-9).

The CICA would grant EPA only 90 days, with the possibility of a 90-day extension, to determine the safety of a new chemical upon receiving notice from a manufacturer or processor. Section 5 (pp. 20-21). If EPA failed to make a safety determination within that timeframe, the applicant would be able to manufacture and market the new chemical. Section 5 (p. 23, line 16 - p. 24, line 5). (As noted in Section 8 of this memo, states would be largely preempted from regulating a new chemical after this review period expires.) Additionally, even in cases where EPA concludes more information is needed evaluate the safety of a new chemical, the agency would have the discretion to allow the chemical on the market before receiving additional information about its safety. Section 5 (p. 22, line 20-25).

The CICA also would exempt several classes of chemicals from the new chemical review process including those for test marketing or those that exist temporarily. (p. 27, line 17 – p. 32, line 2). The CICA would go on to exempt chemicals used “as part of an article” from being considered a significant new use unless EPA could show that the new use presents an unreasonable risk of harm. Section 5 (p. 18, line 21 - p. 19, line 12). The practical implications of this provision remain unclear but raise concerns from a public health perspective.

5) No priority review for some of the chemicals of greatest concern.

The CICA does not specifically require EPA to prioritize persistent, bioaccumulative, and toxic (PBT) chemicals, chemicals detected in adults and children through biomonitoring studies, or chemicals that carry a greater risk of harm for vulnerable populations as compared to the general public. *See* Section 6 (p. 34, line 9 – p. 35, line 18). The assessment and regulation of such chemicals must be made a top priority in any TSCA reform measure.

6) Retains TSCA’s weak safety standard, requires onerous cost-benefit analysis.

The CICA would mostly preserve the problematic “unreasonable risk” of harm safety standard found in current law, but would limit EPA’s considerations to risk under a chemical’s “intended conditions of use.” Section 6 (p. 37, lines 8-17; p. 39, line 19 – p. 40, line 2). This “unreasonable risk” language has been interpreted by courts and legal experts as requiring onerous cost-benefit analysis, and, therefore, is not a truly health-based standard.

The CICA also would create numerous requirements for EPA to follow when making a safety determination that would further impede the agency's ability to manage chemical risks. For example, EPA would be required to: (1) employ "best available science," an innocuous term on its face, but one that could exclude highly relevant science, as described in Section 2 of this memo; (2) describe appropriate "modes of action," which often do not exist, and which may result in the exclusion of occupational and epidemiological studies on associations between chemicals and disease where a mode of action has not been identified; and (3) consider whether to identify "threshold doses," which may impede the regulation of chemicals with low dose effects. *E.g.*, Section 6 (p. 37, line 21 – p. 38, line 21).

The CICA would prevent EPA from performing safety determinations on chemicals designated as "low priority" (unless re-designated, although the draft is unclear on re-designation might occur). Section 6 (p. 35, lines 19-22). The practical effect of this is that a large number of existing chemicals would likely never be evaluated for safety.

Finally, the CICA would impose layers of cost-benefit analysis on EPA before the agency could take risk management steps on a chemical (e.g., warnings, record-keeping, phase-outs, bans). Specifically, EPA would have to consider the proportionality of risks, net benefits, cost-effectiveness, and, in the case of bans or substantial limits on use, technically and economically feasible alternatives. Section 6 (p. 43, line 8 – p. 44, line 14). If the experience with TSCA is any indication, these requirements could make it nearly impossible for EPA to phase out or ban a hazardous chemical that is harming public health and the environment.

7) Overly broad allowances for confidentiality claims.

The CICA includes overly broad allowances for confidential business information that undermine the public's right to know about the chemicals they are exposed to on a daily basis.

Justification and Substantiation: The CICA would only require companies to substantiate confidentiality claims for the specific identity of a chemical, and not for other kinds of information. Section 14 (p. 66, line 8 – p. 67, line 22) (apparent drafting error on p. 66, line 15, which references paragraph (a)(8) instead of what should be (a)(7)). Companies should be required to justify and substantiate all claims of confidentiality so that EPA may determine if the claim is warranted. Chemical identity should be ineligible for confidentiality status, as not having that information greatly reduces the understanding and applicability of health and safety data by not allowing scientists and academics to readily know which chemical certain health and safety data is tied to.

Indefinite Time Period for Protection: The CICA would require EPA to protect information claimed as confidential unless: a company withdraws a claim; the agency finds the information has been publicly disclosed or no longer meets the criteria for protection; or, in the case of chemical identity, the time period for which a company has requested protection has expired. Section 14 (p. 72, lines 9-24). Claims of confidentiality should be subject to an automatic sunset, requiring companies to justify and substantiate a need for continued protection after a reasonable period of time such as 5 years.

Grandfathering of Existing Claims: If enacted into law, the CICA would not allow EPA to require reestablishment of confidentiality claims made before its enactment, except in limited circumstances. Section 15 (p. 73, lines 5-13). The CICA would therefore effectively grandfather thousands of unsubstantiated claims that currently exist. Both existing and new claims of secrecy should be subject to justification and substantiation requirements.

Restrictions on Sharing of Information by Health Professionals: Although the CICA contains explicit provisions that would allow treating physicians and nurses and other health professionals to obtain under certain circumstances confidential information — an improvement to current law — the provisions would require them to sign a written agreement stating that they will not use the information for any purpose other than to treat a specific individual who has been exposed to a chemical substance. Section 15 (p. 70, line 9 – p. 71, line 16). Medical professionals must have greater leeway to share confidential information about hazardous chemicals that have caused harm to protect the public health.

8) Sweeping preemption language severely limiting state efforts to regulate chemicals.

The CICA's sweeping preemption language, Section 17 (pp. 78-80), would drastically curtail states' ability to regulate chemicals to protect public health and the environment. This effect — combined with the numerous burdens the CICA would impose on EPA — would undoubtedly create a regulatory framework that is worse than current law. This is particularly true given the fact that most of the activity to ensure chemical safety over the past three decades has occurred at the state level.

Specifically, the CICA would prevent states from creating new, or enforcing existing, laws that require the development or submission of chemical information once EPA has requested it under its various test authorities (i.e., general, for new and existing chemicals, and for significant new uses). Section 17 (p. 78, lines 6-14). States would be unable to require the development or submission of information related to a chemical for which EPA has made a safety determination — even if EPA has yet to issue a corresponding risk-management rule should a chemical fail the safety standard. Section 17 (p. 78, lines 15-18).

The CICA would preempt states from regulating chemicals in many other respects, as well. The preemption section would block states from prohibiting or restricting in any way the manufacture, processing, distribution, or use of a chemical (e.g., warning labels, green chemistry program requirements) once EPA determines that a chemical is likely to meet the safety standard; issues a risk-management rule for a chemical; or simply designates a chemical as low priority. Section 17 (p. 78, line 19 – p. 79, line 15). The mere expiration of a review period for a new chemical would trigger this broad preemptive effect, regardless of whether EPA makes any sort of finding with respect to a chemical. Section 17 (p. 79, lines 19-22). Also gone would be state notification requirements for new chemicals or significant new uses once EPA requires them for a chemical. Section 17 (p. 79, line 23 – p. 80, line 2).

Further, states would be unable to enforce new or existing laws for chemicals subject to EPA rules in effect before CICA passage. Section 17 (p. 80, lines 3-10). The language on this

point suggests that even non-TSCA-related rules would have a preemptive effect. If so, this raises serious questions about the fate of state programs in place to regulate waste management of toxic chemicals such as PCBs, were the CICA to become law.

Although the CICA includes a provision that purports to preserve private causes of action under state law for injuries or property damage caused by chemicals, the language is unduly vague. Section 17 (p. 80, lines 20-24). For example, this section is unclear about whether state attorneys general could seek enforcement action against a chemical company on a non-statutory basis.

9) Retains the onerous standard of review contained in current law.

The CICA uses the same heightened 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 18 (p. 83, lines 15-19). This standard is considered more rigorous than the standard of review typically applied to agency actions, which only requires an agency to show that it acted reasonably. As the U.S. Court of Appeals for the Fifth Circuit noted in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (1991) (a ruling prevented EPA from banning asbestos under TSCA), this standard of review “imposes a considerable burden” on EPA to develop a record that can withstand a hard look from courts.

10) Lacks provisions for fees and cost-sharing.

The CICA does not give EPA the authority to require reasonable fees from the chemical industry to help defray the costs of ensuring the safety of chemicals.

11) No sections on hot spots, green chemistry, children’s health research, or sharing information with international regulators.

Previous TSCA reform bills (e.g., Safe Chemicals Act) included specific sections addressing hot spots, or locations with disproportionately higher exposure levels to chemicals, children’s environmental health research programs, incentives to encourage the development of safer alternatives to existing chemicals through green chemistry, and the need for cooperation with international regulators to share information about chemical risks. The CICA fails to address these important issues.

12) Lack of meaningful deadlines.

The CICA has few concrete deadlines and creates numerous opportunities for delaying the assessment and regulation of chemicals (e.g., no timeframe for prioritizing or evaluating chemicals). This could lead to decades-long assessments as the chemical industry seeks to delay and restart assessments with which it does not agree.