



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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OFFICE OF CONGRESSIONAL AND  
INTERGOVERNMENTAL RELATIONS

The Honorable John Shimkus  
Chairman  
Subcommittee on Environment and the Economy  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for the opportunity to respond to the questions for the record following the April 29, 2014, hearing on the discussion draft entitled the "Chemicals in Commerce Act." Enclosed are the EPA's responses to the questions.

If you have any further questions, please contact me or your staff may contact Sven-Erik Kaiser in my office at [kaiser.sven-erik@epa.gov](mailto:kaiser.sven-erik@epa.gov) or (202) 566-2753.

Sincerely,



Nichole Distefano  
Deputy Associate Administrator  
Office of Congressional Affairs

Enclosure



NOV 2 2014

UNIVERSITY OF CALIFORNIA, BERKELEY  
THE GRADUATE SCHOOL

THE UNIVERSITY OF CALIFORNIA, BERKELEY  
THE GRADUATE SCHOOL  
1200 UNIVERSITY AVENUE, SUITE 1000  
BERKELEY, CALIFORNIA 94720-1000  
TEL: (415) 495-1000 FAX: (415) 495-1001  
WWW.UGS.BERKELEY.EDU

THE UNIVERSITY OF CALIFORNIA, BERKELEY  
THE GRADUATE SCHOOL  
1200 UNIVERSITY AVENUE, SUITE 1000  
BERKELEY, CALIFORNIA 94720-1000  
TEL: (415) 495-1000 FAX: (415) 495-1001  
WWW.UGS.BERKELEY.EDU

*John Doe*

1200 UNIVERSITY AVENUE, SUITE 1000  
BERKELEY, CALIFORNIA 94720-1000  
TEL: (415) 495-1000 FAX: (415) 495-1001  
WWW.UGS.BERKELEY.EDU

1200 UNIVERSITY AVENUE, SUITE 1000  
BERKELEY, CALIFORNIA 94720-1000  
TEL: (415) 495-1000 FAX: (415) 495-1001  
WWW.UGS.BERKELEY.EDU

House Committee on Energy and Commerce  
Subcommittee on Environment and Economy  
Hearing on "Chemicals in Commerce Act"  
April 29, 2014  
Questions for the Record

**The Honorable Henry A. Waxman**

**Waxman 1. Despite testimony over the past seven hearings on TSCA that the new chemicals program under current law has largely been a success, the revised draft implements a number of substantial changes to this program. These include new exemptions for articles and byproducts, as well as a new analytical standard under which EPA must determine whether or not regulation "is warranted." The purpose and effects of these changes are not clear.**

**Do other laws implemented by EPA require determinations of whether regulation "is warranted?" If so, has that standard been interpreted in the past as requiring a cost-benefit analysis? Has the "is warranted" standard posed any difficulties for implementation?**

**Response:** As noted below, the EPA identified the phrase "is warranted" (or a close variant) in several statutes it administers. Setting aside a statutory provision concerning motor vehicle warranties under Clean Air Act section 207 (using "warrant" in a different sense), the identified references are as follows:

- The Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(g)(2)(C) discusses revisions to certain previously issued regulations or orders that are "found to be warranted" after reviewing the arguments of the parties in a proceeding under FFDCA section 408(g)(2). There is also language in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 4(g)(2)(E)(v) relating to such follow-up proceedings under FIFRA or the FFDCA as "are warranted," in light of a reregistration decision. In both cases, the EPA interprets "warranted" as a direction to act in a manner that is appropriate and consistent with the underlying statutory standards that are being administered under FIFRA or the FFDCA. The EPA has not interpreted this phrase as altering or impeding the implementation of the underlying statutory standards of FIFRA or the FFDCA.
- The use of "warranted" in the Emergency Planning and Community Right-To-Know Act (EPCRA) section 313(b)(2) relates to the application of reporting requirements to additional facilities where such action "is warranted." The EPA has never used this authority and thus has never formally interpreted "is warranted" for the purposes of this provision.
- The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) section 116(b) authorizes the EPA to evaluate contaminated sites on a

database “if such evaluation is warranted” for possible listing on the National Priorities List (NPL). The EPA has not stated how it interprets the phrase “if such evaluation is warranted.” The EPA has not interpreted it to provide for any cost-benefit analysis. CERCLA section 104(k)(3)(A)(ii) provides for the EPA to establish a program to provide cleanup grants to “eligible entities or nonprofit organizations, *where warranted*, as determined by [EPA] based on considerations [set forth in] subparagraph (C).” (emphasis added). Section 104(k)(3)(B) provides that eligible entities who receive a grant may in turn give cleanup sub-grants to other eligible entities or nonprofit organizations, “where warranted.” Subparagraph (C) further provides a number of considerations for the EPA to consider in determining whether a grant “is warranted.” The EPA does consider certain benefits as required by the considerations listed in section 104(k)(3)(C) (e.g., extent to which a grant will facilitate the creation or preservation of parks).” Pursuant to these provisions, the EPA has developed proposal guidelines for grants which contains ranking criteria. Applicants respond to the ranking criteria in their proposals, and proposals that pass threshold criteria review are then evaluated and scored by national panels. Proposals are selected for awards based on these scores, the availability of funds, and other factors. The EPA has not interpreted this provision to require any cost-benefit analysis.

- This phrase appears in the Safe Drinking Water Act (SDWA) section 1458(c), as part of a requirement for the EPA to complete certain studies to support development of rules that have since been completed. Those studies were to include toxicological investigation, as well as “if warranted” epidemiological studies, related to disinfectants and disinfectant byproducts.

**Waxman 2. In your written testimony, you suggested that these new changes would have an adverse effect on the new chemicals program, weakening current law.**

**For instance, you state that EPA’s risk management authorities for new chemicals under the discussion draft would be weaker than those in current TSCA.**

**Please explain this concern in detail.**

**Response:** Under the current Toxic Substances Control Act (TSCA) section 5(e), when the EPA has insufficient information on a new chemical substance, the EPA may issue a proposed order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance, either where such substance “may present an unreasonable risk,” [TSCA section 5(e)(1)(A)(ii)(I)], or where the substance will be produced in substantial quantities and there is sufficient potential for environmental release or human exposure [TSCA section 5(e)(1)(A)(ii)(II)].

The draft of the Chemicals in Commerce Act (CICA) section 5(c)(5) appears to limit risk management actions for new chemicals to those circumstances where the EPA could establish (within the applicable review period allowed for reviewing a pre-manufacturing notice) that a particular action is “necessary to protect adequately against an unreasonable risk.” This is a more demanding standard than either of the current risk management standards for new chemicals in TSCA section 5(e).

**Waxman 3. The draft also weakens current law with respect to EPA's ability to respond where there is insufficient information. Under current law, when EPA receives a PMN for a new chemical and finds that there is insufficient information to evaluate the chemical's risks, EPA has a number of options, including requiring the development and submission of test data pursuant to section 4. The draft would curtail some of these authorities.**

**What steps would EPA have to take under the revised draft to obtain the information needed for new chemical reviews?**

**Response:** With respect to circumstances where the Administrator finds that additional information is necessary in order to review a pre-manufacture notice, CICA section 5(c)(2)(B)(i) appears to specify that the EPA must first provide an opportunity for the submitter of the notice to voluntarily submit the additional information and/or voluntarily extend the review period. Where this is unsuccessful, under CICA section 5(c)(5) it appears that the EPA would next need to determine (within the remainder of the applicable review period) that the development of additional information was "necessary to protect adequately against an unreasonable risk."

**Waxman 4. Would these steps take additional time and/or resources, compared to the current process, and if so, what effects could that have?**

**Response:** The EPA has not undertaken an exercise to estimate the time or resources that would be needed to implement CICA, compared to the current process.

**Waxman 5. There has been consensus among a broad group of stakeholders that chemicals should be held to a risk-based safety standard under a reformed TSCA. This has been part of EPA's principles for TSCA reform since 2009. You testified that the standard in the discussion draft is a "risk/cost balancing" standard similar to what exists under current law and that it "does not align with the approach delineated in [EPA's] principles."**

**At the same time, you testified that EPA needs to have the flexibility to consider costs in risk management.**

**In EPA's view, should costs of risk management options play a role in determining whether or not a chemical meets a risk-based standard?**

**Response:** As stated in Principle 1 of the "Essential Principles for Reform of Chemicals Management Legislation" (<http://www.epa.gov/oppt/existingchemicals/pubs/principles.html>), the EPA should have clear authority to assess chemicals against a risk-based safety standard based on sound science and risk-based criteria protective of human health and the environment, which would not include a consideration of costs.

**Waxman 6. In EPA's view, should the Agency have discretion to consider costs in choosing among available risk management options that would be adequate to bring a chemical into compliance with a risk-based standard?**

**Response:** As stated in Principle 3 of the “Essential Principles for Reform of Chemicals Management Legislation”, when addressing chemicals that do not meet the safety standard, the EPA should have the flexibility to make risk management decisions that take into account a range of considerations, including children’s health, economic costs and availability of substitutes, social benefits, and equity concerns.

**The Honorable John D. Dingell**

**Dingell 1. In 1976, I submitted report language in regard to weaknesses that existing in the current Toxic Substances Control Act. I stated it was essential for the protection of public health and environment that EPA have a firm mandate for a comprehensive approach to protection from hazards due to chemical substances. And, that such a success could only be achieved through legislative directions and adequate support funding. Mr. Jones, you state in your testimony that, in order to be successful, EPA must have the resources it needs to protect the American people from exposure to harmful chemicals.**

**Dingell 1a. Under CICA, does EPA have the appropriate resources to quickly and efficiently implement the various framework, process, criteria, and guidance provisions which must be in place prior to EPA beginning action on specific chemicals?**

**Response:** CICA does not include provisions to collect fees. As outlined in the Administration’s TSCA Reform Principles, implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that the EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of agency implementation, including the review of information provided by manufacturers.

**Dingell 1b. Under CICA, once EPA is able to take action on a specific chemical, does EPA have the resources needed to quickly and efficiently determine prioritizations, assessments, determinations, and risk managements?**

**Response:** The EPA has not yet assessed the resources that would be required to take action under CICA.

**Dingell 2. EPA has over 84,000 chemicals listed on its TSCA inventory, and little over 200 have been acted on in 37 years. EPA has identified an initial work plan of chemicals for assessment which includes 83 substances, in addition to identifying several hundred chemicals on the Safer Chemicals Ingredients List.**

**Dingell 2a. Under current TSCA, does EPA have the appropriate resources to complete more than 20 risk assessments per year on existing chemicals? Please answer yes or no.**

**Response:** No.

**Dingell 2b. What kind of resources would EPA need in order to perform 10 to 20 more additional risk assessments per year?**

**Response:** With current resources, the EPA is able to produce about ten assessments a year.

**Dingell 3. As you know, I have the privilege to live in the Great Lakes region, home to 20 percent of the world's fresh water supply as well as tremendous hunting and fishing areas. Many of my constituents have voiced concerns that CICA does not ensure adequate public health and safety standards needed for highly toxic chemical contamination found in this region.**

**Dingell 3a. Would EPA be better able to regulate new and existing chemicals if they were granted the authority to set priorities for conducting safety reviews based on relevant risk and exposure conditions?**

**Response:** As outlined in Principle 4 of the "Essential Principles for Reform of Chemicals Management Legislation," the EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations.

**Dingell 3b. If both chemical manufacturers and EPA had the ability to assess and act on priority chemicals like those potentially found in the Great Lakes, would EPA be better able to regulate those chemicals in a timely manner?**

**Response:** As outlined in the Administration Principles, the EPA should have the ability to assess and act on priority chemicals in a timely manner.

