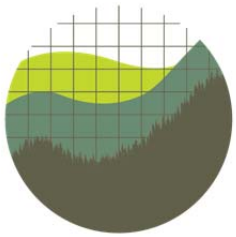

Institute *for*
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

March 20, 2017

VIA ELECTRONIC SUBMISSION

Environmental Protection Agency

Attn: Susanna W. Blair, Immediate Office, Office of Pollution Prevention and Toxics

Re: EPA–HQ–OPPT–2016–0654, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act

The Institute for Policy Integrity ("Policy Integrity") at New York University School of Law[1] respectfully submits the following comments to the Environmental Protection Agency ("EPA" or the "Agency") regarding its proposed process for conducting risk evaluations under recent amendments to the Toxic Substances Control Act ("TSCA").[2]

Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy. Our comments and recommendations are as follows:

- EPA should make clear that, although it may not consider costs when deciding whether a chemical substance poses an unreasonable risk, it *must* take costs and benefits into account when deciding how stringently to regulate that substance.
- EPA should implement a consistent approach to evaluating cancer and noncancer risks.

I. EPA should make clear that, although it may not consider costs when deciding whether a chemical substance poses an unreasonable risk, it *must* take costs and benefits into account when deciding how stringently to regulate that substance.

EPA appropriately notes that the amended TSCA expressly precludes the agency from considering costs when determining whether a chemical substance presents an

[1] This document does not purport to present New York University School of Law's views, if any.

[2] 82 Fed. Reg. 7562 (Jan. 19, 2017).

"unreasonable risk of injury to health or the environment."[3] But the Agency should make clear that the statute's cost preclusion applies only to this threshold inquiry, when EPA is deciding, in essence, whether *any* regulation of a chemical substance is warranted. Once the agency proceeds to a determination of *how much* regulation is necessary, it not only can but must consider both the costs and benefits of available risk-management techniques.

At the risk-management stage, EPA must regulate "to the extent necessary so that the chemical substance or mixture no longer presents" an unreasonable risk.[4] When "selecting among prohibitions and other restrictions," TSCA instructs EPA to "factor in, to the extent practicable" "the reasonably ascertainable economic consequences" of any rule, including "the costs and benefits of the proposed and final regulatory action" and the "primary alternative regulatory actions" considered by the Agency.[5] In keeping with this statutory directive, EPA should strive to set the stringency of its TSCA regulations at levels that maximize social welfare. Thus, EPA should not find that a regulatory action addresses an unreasonable risk "to the extent necessary" if an alternative action would provide greater net benefits to society.

Consistent with the Office of Management and Budget's Circular A-4 and EPA's internal guidelines for economic analysis, any assessment of the costs and benefits of a regulatory alternative should take into account its likely indirect effects—positive and negative—as well as anticipated effects that are not reasonably susceptible to quantification.[6]

II. EPA should implement a consistent approach to evaluating cancer and noncancer risks.

Traditionally, EPA has used a "margin of exposure" ("MOE") approach to estimate noncancer risks, which assumes that noncancer risks have some exposure level below which there are no adverse health effects to the exposed population.[7] If (after accounting for uncertainty) the observed exposure level is below this threshold level, then EPA concludes that adverse noncancer risks are unlikely for the exposed population and essentially values any risk reduction below the threshold level at zero.

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[3] 15 U.S.C. § 2605(b)(4)(A); *see also* 82 Fed. Reg. at 7566 (discussing statutory bar on cost consideration and requesting comment).

[4] 52 U.S.C. §2605(a).

[5] *Id.* § 2605(c)(2).

[6] *See* Office of Mgmt. & Budget, Exec. Office of the President, OMB Circular A-4, Regulatory Analysis at 2, 26 (2003); EPA, Guidelines for Preparing Economic Analyses at 7-1, 11-2 (2010); *see also* Policy Integrity, The Importance of Evaluating Regulatory "Co-Benefits" (2017), http://policyintegrity.org/files/media/Co-Benefits_Factsheet.pdf.

[7] 82 Fed. Reg. at 7572 (requesting comment on the strengths and weaknesses of the margin-of-exposure approach).

As discussed by the National Academy of Sciences, assuming a population threshold is questionable for most chemicals.[8] First, there is variability in human susceptibility.[9] Second, "[n]oncancer effects do not necessarily have a threshold."[10] As a result of EPA's treatment of noncancer risks, these risks "have been underemphasized, especially in benefit-cost analyses."[11]

Instead, EPA should implement a consistent approach to evaluating cancer and noncancer risks that includes assessment of background exposures, possible vulnerable populations, and exposure pathways that might affect the dose-response relationship.[12] According to the National Academy of Sciences, "[s]cientific and risk-management considerations both support unification of cancer and noncancer dose-response assessment approaches."[13]

EPA's descriptions of its plans for hazard and exposure assessments under the amended TSCA, including dose-response assessments and characterizations of the weight of evidence, are encouraging.[14] EPA should make clear that such assessments will apply not only to cancer risks but also to noncancer risks.

Respectfully,

Caroline Cecot
Jack Lienke

Institute for Policy Integrity

[8] Committee on Improving Risk Analysis Approaches Used by the US EPA, Science and Decisions: Advancing Risk Assessment at 6-7, 8-9 (National Academies Press, Washington, DC 2009).

[9] *See id.* at 6-7.

[10] *Id.* at 8.

[11] *Id.*

[12] *See id.* at 9 (recommending a consistent, flexible, and unified approach for evaluating cancer and noncancer risks).

[13] *Id.*

[14] 82 Fed. Reg. at 7570-71.