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(Viewpoint): Science Should Guide TSCA Reform

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1 **(VIEWPOINT): SCIENCE SHOULD GUIDE TSCA REFORM**

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11 The Toxic Substances Control Act (TSCA) of 1976 tasks the U.S. Environmental Protec-
12 tion Agency (EPA) with managing chemical safety in the United States. TSCA works by a sys-
13 tem of pre-manufacture notifications (PMNs), which are submitted to the EPA by industry when
14 a company wants to market a new chemical or an old one for a new use. The notification to the
15 EPA includes information on the chemical's composition and intended use. However, one of the
16 major shortcomings of TSCA is the lack of health testing of new chemicals. If a company has
17 any toxicity data, they are required to submit the data with the PMN, but there are no require-
18 ments to collect health data prior to PMN submission. After reviewing the PMN, the EPA then
19 responds with permission to produce or market the chemical, a request for additional data, or
20 with a denial. Certain substances are generally excluded from TSCA, such as foods, drugs, cos-
21 metics, and pesticides.¹

22 TSCA has not been as effective as originally hoped; in fact, some refer to it as the Toxic
23 Substances *Conversation* Act in tribute to its slow pace. Reform is needed. Much has changed

24 since 1976. PCBs, DDT, mirex, and endosulfan are no longer on the market; the Stockholm
25 Convention on persistent organic pollutants (POPs) has come into force; and the European Union
26 has passed sweeping legislation focused on chemical safety called Registration, Evaluation, Au-
27 thorization and Restriction of Chemicals (REACH).²

28 TSCA reform is underway. Stakeholders in this effort include governmental, industrial,
29 non-governmental organizations, and academic scientists. While many scientists typically avoid
30 the political process, we maintain that the scientific community has valuable expertise and must
31 be at the table as TSCA is rewritten. With scientific input, the U.S. can learn from past mistakes
32 and benefit from decades of research on chemical fate and effects.

33

34 What are the key elements to a reformed TSCA?

35 **1. “Innocent until proven guilty” should not apply to chemicals.** TSCA is based on
36 the assumption that a chemical is safe until proven harmful. This is a fatal flaw. Numerous stud-
37 ies have suggested that there are hundreds to thousands of chemicals that have the properties of
38 POPs.³ New legislation needs to turn the proof of chemical safety over to manufacturers. No
39 agency is capable of adequately assessing all chemicals for their safety. It is the manufacturer’s
40 responsibility to demonstrate safety of their product, and the EPA’s role to critically review these
41 assessments. This is how REACH is designed.²

42 **2. “Grandfathering in” of chemicals spells trouble for the future.** When TSCA was
43 implemented in 1976, substances that were or had been produced at that time were exempt from
44 the legislation. Obviously, it was in the chemical industry’s best interests to have as many of
45 their products or potential products on this list as possible, and as a result, at least 50,000 sub-
46 stances were exempted from regulation. These exemptions formed the initial TSCA Inventory,

47 and these exemptions must be re-assessed. REACH provides a mechanism for exemptions, but
48 requires industry to justify the need for an exemption..²

49 **3. Single-compound replacements are no alternative for structural reform.** When
50 polybrominated biphenyls (PBBs) contaminated Michigan in 1977, they were withdrawn from
51 the flame retardant market and replaced by polybrominated diphenyl ethers (PBDEs). When the
52 environmental ubiquity of PBDEs became apparent in 2000, they were withdrawn from the mar-
53 ket and replaced by polybrominated benzoate and phthalate esters.⁴ This stepwise approach is
54 not sustainable in the long term, and indeed, the flame retardant industry is shifting to products
55 that save lives but do not leak into the environment.

56 **4. There are many biological and ecological endpoints to consider.** Toxicology is a
57 difficult science. What toxic effects should one consider? How does one evaluate long-term
58 chronic exposures? How can particularly sensitive populations (e.g. young and elderly) be pro-
59 tected? Can biochemical, proteomic, or genomic experiments (vs. whole animal experiments) be
60 used for regulatory purposes? Any changes to TSCA should recognize these challenges and be
61 less proscriptive and more holistic.

62 **5. Mixtures of chemicals may have greater environmental impacts than the chemi-
63 cals alone.** Traditional legislation has focused on a single chemical at a time. Yet environment
64 exposures occur in complex mixtures. Key studies have shown that a cocktail of many individ-
65 ual compounds below their respective no observed effect levels can still result in significant ad-
66 verse effects.⁵ While TSCA is currently designed to evaluate chemicals independently, many
67 chemical manufacturers sell their products as mixtures; therefore, evaluations should be con-
68 ducted not only on individual chemicals, but also on the marketed mixture. It is also important
69 to assess the toxicity of impurities in mixtures.

70 **6. Restrictions on access to proprietary information submitted to the EPA by industry**
71 **should not be permanent.** TSCA does not limit the period in which a chemical can be consid-
72 ered proprietary or trade secret. In the pharmaceutical arena, new drugs are patented for up to 20
73 years, providing drug company time to recoup its research investment and make a profit. When
74 the patent expires, other companies can produce generic versions of the drug. This arrangement
75 is a suitable compromise between industry's right to a protected market and the public's right to
76 less-costly drugs. Within TSCA, the chemical industry should have a limited time during within
77 which the information submitted to the EPA will be considered proprietary. After this time, in-
78 formation should be publicly available. Site-specific production volumes should also be publicly
79 available after a reasonable embargo. In addition, because research on many chemicals is hin-
80 dered by a lack of authentic standards, samples of any chemical substance produced or imported
81 into the United States should be archived in a national repository funded by the chemical indus-
82 try.

83 **7. Scientists are willing to help.** Many of us have dedicated their professional lives to
84 better understanding chemicals' environmental concentrations, properties, transport, fates, and
85 effects. Can we afford to just stand-by? If TSCA is not reformed, the unrestricted production,
86 use, and release of unsafe chemicals could continue, and with it the on-going exposure of the
87 American public to a complex mixture of these chemicals. We have an obligation to make our
88 voices heard and to promote proven scientific principles as a basis for TSCA reform. We can do
89 this through our scientific organizations and via our representatives in Congress.

90

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