

September 10, 2013

The Honorable Richard Blumenthal
Chairman, Subcommittee on Oversight, Federal Rights, and Agency Action
U.S. Senate Committee on the Judiciary
724 Hart Senate Office Building
Washington DC 20510

The Honorable Orrin Hatch
Ranking Member, Subcommittee on Oversight, Federal Rights, and Agency Action
U.S. Senate Committee on the Judiciary
104 Hart Senate Office Building
Washington DC 20510

Re: Delays in Regulatory Reviews by the Office of Information and Regulatory Affairs (OIRA)

Dear Chairman Blumenthal and Ranking Member Hatch:

Environmental Defense Fund, Earthjustice, Union of Concerned Scientists and League of Conservation Voters appreciate your leadership in convening the August 1, 2013, hearing, Justice Delayed: The Human Cost of Regulatory Paralysis. We share the deep concern expressed by several of the witnesses at the hearing about the real-world consequences of the extensive delays in regulatory reviews that have become routine at the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB).

We are encouraged, however, by your commitment to further investigate these issues. We write to recommend you consider holding a hearing focused on rulemakings proposed under the Toxic Substances Control Act (TSCA) as one of the many egregious examples of chronic delays in OIRA reviews of rulemakings proposed by the U.S. Environmental Protection Agency (EPA).

TSCA, passed in 1976, was intended to give EPA authority to assess, and where necessary regulate, chemicals in commerce in order to protect human health and the environment. Unfortunately, this law has proven ineffective and both industry and public interest stakeholders have been urging it be reformed. The consideration by this Congress of legislation to reform TSCA may finally open a path forward to improve this outdated law.

Even as reform legislation is being debated, however, EPA has sought to use its limited authority under current TSCA to propose relatively modest rules and other actions that are primarily aimed at increasing the amount and availability of information on the safety of chemicals. Notably, none of these TSCA rulemakings propose to impose any restriction on the production or use of any chemical. These proposed rules would help to ensure that businesses and consumers have access to better information

concerning the potential risks posed by commercial and industrial chemicals and can make more-informed market decisions.

Yet, again and again, these rules have been held in regulatory limbo, either indefinitely or for far longer than the time allotted for OIRA reviews under Executive Order 12866. The allotted time periods as stated in Section 6(b)(2) of the Executive Order are as follows (emphases added):

“(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, **within 10 working days** after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, **within 90 calendar days** after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by **no more than 30 calendar days** upon the written approval of the Director and (2) at the request of the agency head.”

Since 2009, a total of 33 TSCA-related notices or proposed or final regulatory actions have been submitted to OIRA.

- Fifteen of these were advance notices of proposed rulemakings or other notices subject to the 10-working-day deadline. Of these notices, **only one** was completed within this deadline; on average, they were kept under review by OIRA for **over 70 working days**.
- The other 18 TSCA-related submissions were proposed or final rules subject to the 90-calendar-day deadline. Reviews of **only six** of these rules were completed within this deadline; on average, they have been held at OIRA for **over 300 days**.

Four proposed rules subject to the 90-day deadline **have never been cleared by OIRA to allow for public comment**. Two of these proposed rules were just withdrawn by EPA in the face of OIRA’s protracted review, while the other two remain under review. Together, they have been held for **an average of over 950 days – more than 2.5 years**.

The two proposed rules that were just withdrawn would have:

- Designated as “chemicals of concern” bisphenol A (BPA), a category of phthalates, and a category of polybrominated diphenyl ethers (PBDEs) – three classes of chemicals for which evidence is more than sufficient to warrant such a designation. By listing a chemical as “of concern,” EPA may obtain, and provide to the public, more information about the chemical than

it is typically able to access. **This proposed rule was withdrawn by EPA after pending before OIRA for more than 1,200 days¹.**

- Clarified, consistent with TSCA, that health and safety studies on new chemicals submitted to the agency cannot be claimed to be confidential business information (CBI), and that those studies along with the identity of the subject chemical should be made publicly available. This information is vital to ensuring the public's and workers' right to know about chemicals to which they may be exposed. **This proposed rule was withdrawn by EPA after pending before OIRA for more than 600 days².**

The proposed rules that are still pending at OIRA would:

- Require manufacturers of engineered nanomaterials to report basic information on their production, processing and use, and to notify EPA prior to manufacturing new nanomaterials or significantly expanding use of existing nanomaterials. The information gleaned is essential to providing EPA with an understanding of the scope of current and emerging nanomaterials so that it can develop an informed approach to identifying and managing any potential risks. **This pair of proposed rules remains at OIRA and their review has been pending for more than 1,000 days³.**

EPA has clear statutory authority to take each of these four proposed actions. There is strong scientific evidence of the actual or potential risks to human health and the environment that may be posed by the kinds of chemicals that would be subject to these proposed rules. And each proposed action would provide EPA, the public and the market with information needed to identify chemicals that could pose risks – without restricting in any manner the production or use of the subject chemicals.

Two of the regulatory actions for which OIRA completed its review only after extensive delays provide additional, particular evidence of the human costs of regulatory paralysis:

(1) Two proposed rules seek to limit emissions of formaldehyde—a known human carcinogen—from composite wood^{4,5}. These proposed rules were **mandated by Congress**, under the Formaldehyde Standards for Composite Wood Products Act passed in 2010. The law required EPA to promulgate **final** implementing regulations by January 1, 2013.

¹ TSCA Chemicals of Concern List Under Section 5(b)(4) of the Toxic Substances Control Act; RIN: [2070-AJ70](#)

² CBI: PMN Amendments Claiming Chemical and Microorganism Identity as Confidential in Data From Health and Safety Studies Submitted Under TSCA Prior to the Commencement of Manufacture; RIN: [2070-AJ87](#)

³ Nanoscale Materials; Reporting Under TSCA Section 8(a); RIN: [2070-AJ54](#)

⁴ Formaldehyde; Third-Party Certification Framework for the Formaldehyde Standards for Composite Wood Products; RIN: [2070-AJ44](#)

⁵ Formaldehyde Emissions Standards for Composite Wood Products; RIN: [2070-AJ92](#)

Despite this statutory deadline, these rules have not yet been finalized and are now eight months overdue and counting. EPA submitted the draft proposed rules to OIRA for review on May 5, 2012. Despite a 90-day deadline for its review, OIRA concluded its review **380 days later**, on May 20, 2013. The proposed rules are now open for public comment. (The original deadline for submitting comments on these proposed rules was August 9, 2013 but is now October 9, 2013 owing to two requests for extensions that EPA granted.)

EPA will then need to develop draft final rules that take into consideration and respond to public comments, before submitting them again to OIRA for review. Barring a record turnaround time for OIRA's review of the draft final rules, we can expect the final rules to finally be promulgated well over a year after the statutory deadline!

(2) As another example, we highlight the July 11, 2013, *Federal Register* notice of EPA's response to a petition submitted under TSCA by 120 environmental and public health organizations⁶. The petition requested that EPA use its TSCA authority to require manufacturers and processors of chemicals used in hydraulic fracturing to develop and report certain safety-related information to the agency so that it can more effectively evaluate the potential risks of these chemicals. The petition was submitted to the agency on August 4, 2011. In November 2011, EPA partially granted the petition and, for those portions of the petition granted, indicated the agency would first proceed with an advanced notice of proposed rulemaking (ANPRM) rather than issuing a proposed rule.

For reasons that remain unclear, EPA has yet to submit a draft of the ANPRM to OIRA for review. But a contributing factor appears to have been OIRA's long delay in clearing the agency's required formal response to the petition for posting in the *Federal Register*—a review that took approximately **404 working days**, despite a deadline of 10 working days for such reviews.

Conclusion

OIRA's refusal to complete some of its reviews, and the long delays in those it has completed, mean that the public is denied its voice in the rulemaking process. That is because the majority of these reviews relate to *proposed* rules for which EPA cannot even solicit and receive public comment on until OIRA's review is completed. Hence the public is blocked from providing input at the very step in the process that is intended to allow concerns or potential flaws in the proposals to be publicly aired so that they can be addressed before such rules are finalized.

⁶ Chemical Substances and Mixtures Used in Oil and Gas Exploration or Production; TSCA Section 21 Petition; Reasons for Agency Response; FR Doc No: [2013-16485](#)

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Indeed, OIRA's protracted holds on these modest (and in some cases statutorily mandated) proposed rules prevents all stakeholders – whether the regulated community, other businesses, workers, consumers or the general public – from providing their perspective on the need for and appropriate shaping of these rules, and it also **prevents or delays EPA from obtaining the information it needs to fulfill its mission to protect human health and the environment.**

We strongly urge your Subcommittee to consider holding a hearing to investigate this issue further, and we would be happy to provide additional information if that would be helpful.

Thank you for your leadership in highlighting and addressing these unwarranted delays that deny the public basic health protections.

Sincerely,

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cc: Senator Patrick Leahy, Chairman, U.S. Senate Committee on the Judiciary
Senator Chuck Grassley, Ranking Member, U.S. Senate Committee on the Judiciary
Sylvia M. Burwell, Director, Office of Management and Budget
Howard Shelanski, Administrator, Office of Information and Regulatory Affairs
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