

New Chemicals Rule: EPA must require more info from industry

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NOTE: This is the third in a series about EPA's regulation of new chemicals. See [Time for a New Age for New Chemicals](#) and [EPA: Now's Your Chance to Get Foxes Out of the Henhouse](#).

What Happened?

EPA recently [proposed regulations](#) to govern how it reviews companies' pre-manufacture notifications for new chemicals before those chemicals can go on the market. These include EPA's proposal to be more specific about the chemical information companies must submit to improve the review process for new chemicals.

Why It Matters

Industry often waits until late in the review process to submit information—which means that EPA may spend a significant amount of time and effort to revise its risk assessments to incorporate the new information.

EPA has a major opportunity to improve the New Chemicals Program as it crafts these revised regulations. Requiring industry to provide additional “known or reasonably ascertainable information” *as required by the law* is an important component of this rule. This should reduce the amount of assessment “rework” the agency currently conducts.

Our Take

EDF supports the aspects of EPA's proposal that clarify, strengthen, and expand on the information required in the initial industry submissions on potential uses, exposures, releases, etc. We also commend EPA for moving to increase efficiency by requiring a more robust submission at the *beginning* of the review process.

The specific information EPA is proposing to require is information companies already have but generally don't include in their initial submissions. A company often submits this information only *after* EPA's review has identified a risk.

While we support EPA's proposed requirement that industry submit more complete information, we noted in [our comments to EPA](#) [PDF, 721KB] that the proposal could go farther in implementing changes needed to ensure the safety of new chemicals and protect human health and the environment, including those people at greatest potential risk.

We encourage the agency to strengthen these requirements further by adding additional information requirements, including:

What EPA Proposed	Our Recommended Revision	Our Rationale
<p>Companies must provide detailed information (i.e., how much of the chemical is used, how frequently it is used and for how long it is used) on intended commercial and consumer uses.</p>	<p>EPA should require submitters to identify the source or basis of this detailed information.</p>	<p>Requiring this source/basis information will help EPA assess the strength of the information industry provides on these key elements—improving the agency’s ability to assess the risk the new chemical presents.</p>
<p>Submitters must use standardized code(s) that best describe the consumer and commercial products in which they plan to use the new chemical.¹</p>	<p>EPA should require companies to submit all the applicable codes (not just the “best”) that represent the largest of the uses for that chemical.</p>	<p>This would: 1) Ensure that EPA assesses risks posed by all known, intended, and reasonably foreseen consumer and commercial uses of the new chemical; and 2) Create consistency with the use of these standardized codes for TSCA Chemical Data Reporting.</p>
<p>Companies must provide certain information on worker exposures, "including descriptions of how workers can be exposed (e.g., inhalation), descriptions of any protective equipment & engineering controls, and description of the physical form(s) of the chemical.</p>	<p>EPA should clarify that the submitter is required to provide worker exposure information for each worker activity (i.e., in manufacturing, processing, and use operations) listed in the submission.</p>	<p>This will help EPA more accurately estimate the risks workers face from the new chemical.</p>
<p>Submitters must report the “quantity of the new chemical substance released to the environment after control technology” and report information on the “amount of release per container cleaning.”</p>	<p>EPA should require submitters to explain the basis/rationale and provide supporting data for the estimates provided.</p>	<p>EPA would have a better basis on which to judge the validity of industry’s estimate.²</p>

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Submitters should provide information on “what is used to clean the equipment.”	EDF recommends that this vaguely worded phrase be modified to provide more clarity: “the cleaning method used, including any devices used and any chemical substance used and the physical state (i.e., solid, liquid, or gas) of the chemical substance.”	This rewording provides better clarity as to what information needs to be provided and is based on text from EPA’s <i>Points to Consider</i> document. ³
Submitters should provide certain information on stack releases to air and for releases to water from facilities with NPDES permits.	EPA should clarify that, for both types of releases, the type of treatment technologies used and the known or expected treatment efficiencies of the technologies be reported. ⁴	This will help EPA better assess release estimates provided by the submitter and developed by EPA.
Submitters should provide information on releases to all wastewater treatment plants (WWTP) not owned by the submitter or by potential processors or users.	Submitters should also be required to provide information, if known, on the use of wastewater “pre-treatment” technologies that the submitter expects to be used to remove/degrade the new chemical prior to discharge to these WWTPs.	This will help EPA more accurately estimate the risks faced by aquatic life and downstream users of the water.

¹ Organisation for Economic Co-operation and Development, Health and Safety Publications. (2017, May 17). *Internationally Harmonised Functional, Product and Article Use Categories*. Paris: OECD Environment, Series on Testing & Assessment ENV/JM/MONO(2017)14, No. 262. [https://one.oecd.org/document/ENV/JM/MONO\(2017\)14/en/pdf](https://one.oecd.org/document/ENV/JM/MONO(2017)14/en/pdf)

² Environmental Protection Agency, Office of Pollution Prevention and Toxics. (2018, June). *Points to Consider When Preparing TSCA New Chemical Notifications*. Washington, DC: OMB Control No.: 2070-0012. https://www.epa.gov/sites/default/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf

³ This information should be known or reasonably ascertainable and is similar to what EPA has long required for Toxics Release Inventory reporting.

⁴ Although such information may be available to EPA from the Clean Water Act and Clean Air Act permit number(s) identified by the submitter, it would require extra effort on EPA’s part to find that information and it may not be obvious from the permit.