

EPA's New Chemical Regulations: Backtracking on PBTs

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NOTE: This is the fifth in a series about EPA's regulation of new chemicals. See:

- [Time for a New Age for New Chemicals](#)
- [EPA: Now's Your Chance to Get Foxes Out of the Henhouse](#)
- [New Chemicals Rule: EPA must require more info from industry](#)
- [EPA's New Chemical Regulations: Industry Bias Must Be Fixed](#)

What Happened?

The Environmental Protection Agency (EPA) recently proposed new regulations for its safety reviews of new chemicals under our nation's primary chemicals law, the Toxic Substances Control Act (TSCA). One of the proposed provisions would govern which persistent bioaccumulative¹ toxic chemicals (PBTs) should undergo a full safety review.

Why It Matters

This proposed approach would exclude certain PBTs from a full new chemical safety review which is a concerning step backward in addressing the risks from these chemicals.

PBT chemicals do not break down readily from natural processes and raise special concern because of their ability to build up in both the environment and in people and other organisms. Even small releases of these long-lived and bioaccumulative toxic chemicals can pose long-term risks to human health and the environment. Notable PBTs—such as DDT, which affects reproduction, and methyl mercury, which is a powerful neurotoxin—impacted whole ecosystems across the United States, including the Great Lakes.



A view of Lake Michigan Photo credit: Maria Doa

¹ Bioaccumulation is the gradual build up over time of a chemical in a living organism. This occurs either because the chemical is taken up faster than it can be used, or because the chemical cannot be broken down for use by the organism (that is, the chemical cannot be metabolized). <https://www.encyclopedia.com/science-and-technology/biology-and-genetics/environmental-studies/bioaccumulation>

Our Take

No PBT should be exempt from a full new chemical safety review.

In 1999, EPA recognized the special nature of new chemicals that are PBTs when the agency issued its PBT policy for TSCA new chemicals. The policy established a comprehensive framework for reviewing and potentially regulating this class of toxic new chemicals based on their persistence and bioaccumulative potential. This policy did not set a criterion for magnitude of exposure, reflecting the long-standing concern that even very small releases of PBTs can be harmful to human health and the environment.

Unfortunately, EPA is backtracking on its 1999 policy by introducing a new criterion: a new chemical must be not only persistent and bioaccumulative but must also have “anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.” Despite the greater potential risks of PBTs, this change makes it more difficult for these chemicals to undergo the standard full new chemical review.

Excluding certain PBTs based on undefined criteria such as “unreasonable exposure” only serves to undermine the review process for these chemicals. What exactly constitutes unreasonable exposure? EPA provides no clear answer. Yet, EPA would make this determination before conducting the necessary analysis.

Moreover, EPA justifies this change by stating that it aligns with its long-standing policy. However, the term “unreasonable exposure” is conspicuously absent – both literally and in spirit - from the 1999 PBT policy.

EPA should take an approach to PBTs in line with the agency’s 1999 PBT Policy, rather than introducing ambiguous terms and excluding certain PBTs from full regulatory scrutiny.

Go Deeper

[Read our previous blogs on PBTs.](#)

Notes

[1] Bioaccumulation is the gradual build up over time of a chemical in a living organism. This occurs either because the chemical is taken up faster than it can be used, or because the chemical cannot be broken down for use by the organism (that is, the chemical cannot be metabolized). <https://www.encyclopedia.com/science-and-technology/biology-and-genetics/environmental-studies/bioaccumulation>