Industry is Scapegoating EPA for New Chemical Review Delays

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What's Happening?

The chemical industry has an extensive—and ongoing—history of complaining about how long it takes EPA to do new chemical safety reviews.

The irony is that industry is the very player causing the delays in EPA's review process. Clear data indicate that chemical manufacturers are primarily responsible for the length of EPA's reviews and the backlog of cases.

Why It Matters

One of EPA's vital roles is to assess the safety of new chemicals before they enter the market. Industry's outcry about a backlog serves as a smokescreen to pressure EPA into swiftly approving new chemicals even when they may not be safe. This would put us all at risk, particularly those who are more susceptible or maybe more highly exposed, such as children, pregnant people, and people who live and work in fenceline communities.

Our Take

A significant factor contributing to delays in the review process for new chemicals is the chemical industry's frequent revisions of their new chemical submissions. These revisions often require that EPA redo/reconduct some or all of a risk assessment, adding several months to the review process. This often involves many rounds of back-and-forth between EPA and the industry.

This challenge prompted EPA to launch an outreach initiative in June 2022. Its aim was to educate and engage stakeholders on this primary source of delay in the new chemical review process and propose strategies to address it. The data presented by EPA clearly indicates that many assessments needed to be revised or reconducted up to five times due to industry revisions after the chemical was first submitted for review.

One critical reason behind these multiple revisions is the chemical industry's failure to provide all the necessary information in their initial submissions.

EPA recently addressed this issue in its proposed regulations to govern how it reviews companies' pre-manufacture notifications for new chemicals. A key aspect of these proposed regulations involves specifying the information required in the industry's initial submissions, particularly about potential uses, exposures, and releases.

However, even these regulatory changes won't resolve all the delays. Often, EPA is left waiting for companies to act or supply the information they've promised.

Data Don't Lie

EPA provides a website that shows the status of each active new chemical case. One look at the site reveals the primary bottlenecks in the system.

- An analysis of the first 100 cases for 2022[1] shows that, of the two-thirds that are still active, **over half** are awaiting action from the *industry* submitters, not from EPA as industry often complains This means the review process cannot progress or conclude until the companies act.
- Among the cases currently with EPA, roughly one-third are undergoing some form of revision, likely due to late information submitted by the industry.
- Many of the remaining cases are at the stage where EPA is figuring out the necessary restrictions to mitigate unreasonable risks, often involving extensive back-and-forth with the industry.

If the chemical industry genuinely wants faster reviews for new chemicals, it should prioritize these reviews and provide submissions that include all relevant information EPA needs to make well-informed, timely decisions.

Go Deeper

Read our previous blogs about EPA's process for reviewing new chemicals.

NOTES

[1] Completed on October 13, 2023.