

Fluazinam exposes failures in the EU's pesticide approval system

The current EU system for approving pesticides is insufficient to reliably protect human health. This is clearly illustrated by the case of fluazinam – a substance that would likely never have received EU approval if studies showing adverse effects on brain development had been accurately reported by the responsible company and rigorously evaluated by regulatory authorities. To achieve a high level of human health protection, regulatory capacity must be strengthened and scrutiny of industry-sponsored chemical safety studies must be increased, rather than reduced as proposed in the Food and Feed Omnibus.

A new scientific analysis of industry-funded toxicity data for the fungicide fluazinam, that is currently undergoing peer review, provides evidence of serious weaknesses in the EU pesticide approval system. Despite the EU's legal commitment to ensure a high level of human health protection, a chain of failures allowed evidence of developmental neurotoxicity to go undetected during the approval and renewal processes.

The analyses re-examined raw data from a company-commissioned developmental neurotoxicity (DNT) study submitted in support of fluazinam's market approval. Scientists identified six instances of false statistical reporting by the testing laboratory that collectively obscured harmful effects on brain development in rat offspring. Significant adverse effects on brain weight and brain dimensions were detectable but went unrecognized by EU and Member State authorities due to inadequate statistical evaluation. These findings are described in a manuscript that has been made publicly available as a preprint (posted on 2 July 2026; [doi: 10.5281/zenodo.21069500](https://doi.org/10.5281/zenodo.21069500)).

The findings highlight several systemic weaknesses in the regulatory process. First, the DNT study was withheld by the pesticide producer from regulatory scrutiny for 15 years. When it was finally submitted, following a request from regulators, the false statistical results were not detected by authority reviewers. Even after the university researchers highlighted strong indications of adverse effects on brain development, the authorities neither conducted nor requested more appropriate statistical analyses. In addition, they applied an insufficiently protective threshold for adverse effects. Had the evidence been known to authorities and properly

RECOMMENDATIONS FOR POLICYMAKERS

- Address resource constraints by increasing regulatory capacity, rather than replacing mandatory renewals with longer or unlimited approvals that risk reducing scrutiny and weakening health and environmental protection.
- Reform the approval system so that toxicity studies are commissioned by public authorities rather than manufacturers, reducing conflicts of interest and preventing reporting bias from influencing regulatory decisions.
- Consider a systematic review of industry-funded studies and regulatory assessment practices across chemicals regulated in the EU. The shortcomings identified in this case are unlikely to be limited to pesticides or developmental neurotoxicity.
- Reduce dependence on chemical pesticides and accelerate the transition to safer and more sustainable alternatives.

evaluated, fluazinam may not have been approved at the EU level in 2008. Its continued use since then may therefore have exposed children to avoidable risks to brain development, particularly those living near fluazinam-treated fields and plantations.

This chain of failures raises broader concerns about a regulatory system that relies heavily on studies commissioned by pesticide manufacturers. Achieving a high level of protection for human health requires that reporting biases and analytical errors are reliably detected, and that authorities are equipped with sufficient resources to stringently evaluate industry-funded studies and assessments, and to follow up on any indications of adverse effects. This is not currently the case. The current “omnibus” suggestion to reduce systematic regulatory scrutiny due to lack of resources and capacity risks worsening the situation further. To protect human health, the EU needs stronger regulatory oversight, greater scientific scrutiny, and more resources for authorities – not deregulation.

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