Pesticide Problems

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The Environmental Protection Agency's (EPA) long-awaited amendments to its experimental use permit (EUP) regulations for microbial pesticides is now available for public comment. Under existing policy, EPA must be notified before all field trials of genetically altered microbial pesticides to determine whether an EUP is necessary, even though naturally occurring or chemical pesticides may be tested in small trials without EPA notification.

EPA review at such an early stage of research has hindered innovation in the development of microbial pesticides for a couple reasons. First, the current policy focuses on the process by which a pesticide is developed, rather than the potential risks it poses, and second, the review imposes delays and uncertainty at a critical stage of product development.

EPA's stated goals in its new proposal seem to recognize the weaknesses of its existing policy. It sets out to focus on the characteristics and risks of the pesticide product, protect human health and the environment without unduly impeding research, and accommodate rapid advances in biotechnology. To accomplish these admirable goals, the agency presents two basic approaches. EPA's preferred approach would require notification for small-scale trials of "microbial pesticides whose pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified." By focusing on pesticidal properties, this option adopts a risk-based element, but it still retains the process-based approach. EPA's alternative approach is more explicitly risk-based. It would require notification for small-scale testing of "indigenous microbial pesticides for which specific pesticidal activities have been created or increased by deliberate processes or techniques," unless the microbe is "unlikely to pose a greater risk in the test site environment" than its parent(s).

Unfortunately, EPA has chosen not to consider an option to return to its pre-1984 policy, which exempted all small-scale field trials from notification. Instead, EPA's preferred option is designed to capture a microbial pesticide if a pesticidal property has been deliberately modified. It would require notification for microbial pesticides developed using specific techniques, such as r-DNA, while excluding products developed from mutagenesis. On the other hand, EPA's alternative focuses on the potential risk of the altered trait; requiring notification for "microbial pesticides that have the potential to pose greater risk because of increased hazard and/or exposure compared to their parental(s)."

There are also procedural differences: EPA's preferred option relies on a centralized approach. It provides a simple criterion for determining whether notification is required; products with enhanced pesticidal properties are covered by the EUP process, unless, after review, EPA gives the researcher a green light to proceed. EPA's alternative approach is more decentralized: the need for notification before a field trial depends on a variety of factors related to the risk of the product in the environment into which it will be introduced. The researcher, after considering EPA's risk guidance, is assumed to be in the best position to judge whether the experiment meets the specified risk criteria.

It is not surprising that EPA prefers the centralized approach since it would give the agency more control over small-scale experiments. EPA argues that the preferred option would lead to "greater consistency," although the most "consistent" approach would be its pre-1984 policy of treating chemical and biological pesticides equally. EPA asserts paternalistically that its preferred option imposes less burden and responsibility on the researcher, who under the alternative would have to evaluate the risk of his experiment before determining whether notification is required. EPA further argues that the agency is better able to judge the potential risks of an experiment than the researcher, based on its "eight years of experience evaluating genetically altered and nonindigenous microbial pesticides." Unfortunately, EPA's track record does not instill confidence in its ability to expedite the availability of safe, reliable microbial pesticides.

New biotechnology techniques promise great gains in the development of safe and effective new microbial pesticides but, so far, government regulation has caused the pace of environmental and agricultural product development to lag behind the rate of innovation in the health area. Unfortunately, EPA's preferred approach in the proposed rule is likely to perpetuate the biases and regulatory delays of the last decade. If EPA is unwilling to put modified microbial pesticides on equal footing with their naturally occurring or chemical counterparts by returning to the pre-1984 policy of exempting small-scale field trials, it should at least adopt a notification scheme that is based explicitly on the potential risks of the experiment. EPA's alternative option provides sound risk-based criteria on which knowledgeable researchers can make decisions about whether their small experiments demand government review.