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THE FIRST WORD

STILL A FEW BUGS IN THE SYSTEM

It was only three years ago that someone first accused us of being a gate-keeper. It came as something of a shock: We had always identified with the scruffy, haunted, leather-elbow-patches, pencil-behind-the-ear cub reporter of film and fiction. "Gate-keeper" sounded more like...well, the image that still comes to mind is Cerberus, the slavering three-headed hell-dog who guarded the gates of Hades. Take it from us, we're not that imposing. (In the legends, of course, heroes seeking entrance into the infernal regions without meeting the stringent entrance requirement—death—traditionally distracted this guardian by tossing him some bread soaked in wine...establishing a tradition savvy publicists follow with the press to this very day.)

The gate-keeper's responsibilities are sometimes troubling, especially when we sense a conflict between the journal's fundamental pro-biotechnology mission and its equally fundamental commitment to open exchange of ideas. Thus, we had to think a bit about "Are B.t.k. plants really safe to eat?" in this issue. The authors (one of whom has observed, probably correctly, that the journal has a pro-industry bias) represent an organization that seems (in addition to its virtues) to have an anti-industry bias. And yet, after scientific review and some deliberation, it seemed that the article should be offered as a consistent exposition of some of the lapses and lacunae in current data and reasoning.

Authors Rebecca Goldberg and Gabrielle Tjaden observe, repeatedly and quite properly, that there is no evidence to suggest that *Bacillus thuringiensis*'s anti-lepidopteran toxin is in any way harmful to other species or the environment. Indeed, there is something very appealing about Nature's packaging of *B.t.* toxin. The bacterium produces the protein in a precursor crystal, which breaks down to release the bioactive moiety itself only in the alkaline environment of the insect gut.

What happens, though, if the active toxin, not the precursor, is engineered into fruits and vegetables? That is a question worth asking—which we have, without receiving any very clear answers about either the precise toxic mechanism or the toxins' effects on mammals. Goldberg and Tjaden offer a more detailed account than we have seen elsewhere.

The authors' final recommendations trouble us, however. Taken together, they seem a prescription not for due caution but for dilatory obstruction. It would be interesting to have some concrete toxicity data on the effects of fully processed *B.t.* toxins on mammals—but decades of experience with the precursor, all without incident, must temper the urgency we feel for obtaining that data.

And whatever the justification for acute toxicity studies, they are in the authors' plan just the first in a line of ever-narrower hoops through which producers of bioinsecticides (and other bio-environmental products) would have to jump.

Each new step requires time and money to design the trials, submit the results to the regulators, and endure "the law's delay, the insolence of office, and the spurns that patient merit of the unworthy takes": What amount to clinical trials—for a food, mind you—to determine whether *B.t.* toxin breaks down in the human gut, and to determine whether the protein passes into the circulatory system. Studies of basic mammalian molecular biology to determine if *B.t.* toxin receptors—not yet firmly identified even in insects—are present in the mammalian gut. Studies in post-translational modification to see if vegetable glycosylation patterns will make the familiar toxin suddenly immunogenic. Ecological and entomological studies to assure that the toxin—concentrated by pollinators—will not damage populations of hymenoptera.

We cannot countenance making this program a precondition for marketing approval. To do so, in a market with agriculture's margins, would assure that no such product is ever marketed...ensuring, too, a continued dependence on chemical pesticides (a point which the authors also make). Existing rules allow us to introduce a product, subject it to whatever scrutiny, and then withdraw it if it appears to be unsafe. And that, here, is by far the wiser course to follow.

—Douglas McCormick