BOOKS: BIOTECHNOLOGY

How Much Caution in the Fields?

Donald N. Duvick

Agricultural biotechnology has enormous potential to help combat hunger.... Biotechnology can help us solve some of the most vexing environmental problems. ... But, as with any new technology, the road is not always smooth. Right now, in some parts of the world there is great consumer resistance and great cynicism toward biotechnology. In Europe protesters have torn up test plots of biotechnology-derived crops and some of the major food companies in Europe have stopped using GMOs—genetically modified organisms—in their products.

Dan Glickman (*1*)
U.S. Secretary of Agriculture

Secretary Glickman is not alone in his concern about the stormy disagreements among scientists and the public over the desirability and safety of transgenic crops. Fervent protests against genetically modified organisms, sometimes accompanied by physical violence, have occurred in most wealthy nations, as well as in some developing countries. Arguments against genetically modified organisms are diverse—they may be based on economic, political, or even religious grounds—but the issue of safety lies at the heart of the disputes. Despite 20 years of work by boards and committees to establish safety guidelines for the testing and release of genetically engineered crops, strong voices continue to insist that the current approval system is flawed. These critics say that existing procedures approve the release of organisms that are potentially dangerous to human health, the environment, or both. Other voices reply that the system works because the released transgenic organisms are indeed safe as certified. Both sides claim that their arguments are based on science.

In *Hazard Identification of Agricultural Biotechnology*, Ad van Dommelen (a Dutch consultant on the environment and economics) proposes a way to resolve the disagreements about safety, at least in regard to the scientific aspects. He argues that the key is to devise a rigorous "set of relevant questions" (SRQ), which he defines as "a collection of research questions that a scientist considers relevant for the study of a specified research problem." These questions will be concerned with hazard identification (identifying a potential bad outcome) rather than with risk analysis (calculating the odds of a bad outcome).

As van Dommelen explains, the set of questions must test all of the assumptions upon which a particular claim of safety (or of danger) is based. The questions should be developed from a broad base of interested parties, not just a narrow group with self-interests in approval for genetically engineered organisms. To this end, nongovernmental organizations and concerned professionals should be solicited for contributions. Parties can argue for or against inclusion or removal of any question, but their arguments must be based on science. Arguments for including a question must be given more weight than arguments to exclude it because "unwarranted exclusion of a possibly relevant research question may have serious unwanted consequences." These lists of questions can and should be modified over time, with the expectation that as experience is gained they can be shortened as well as improved in accuracy. The author suggests procedures for developing a global list of relevant research questions and results, one available for use by authorities in all countries. This list could be the basis for a global network of biosafety expertise.

Hazard Identification of Agricultural Biotechnology
Finding Relevant Questions
by Ad van Dommelen
International Books, Utrecht, The Netherlands, 1999. 238 pp. $29.95, £19.95, Dfl 59.95. ISBN 90-5727-034-X.

Ready for Roundup. The advertising sign proclaims that this field was planted with a herbicide-resistant transgenic soybean variety.

Van Dommelen claims that the underlying basis for biosafety assessment is the precautionary principle. As framed at the 1992 United Nations Earth Summit in Rio de Janeiro, the principle holds that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (*2*). This normative statement provides the basis for a testable scientific claim: "There are threats of serious or irreversible damage." The set of relevant questions addresses this scientific claim to show whether it is true or false. When applying the approach to a genetically modified organism, one must prove that the organism will not cause serious or irreversible damage, otherwise it should not be released. Therefore the question sets should be designed to ensure recognition and avoidance of Type-II error—a conclusion of "no observed effect" when in actuality there is an effect (such as environmental damage from a wandering transgene).

A simpler way of expressing the precautionary principle as applied to transgenic organisms may be the following "moral imperative," which van Dommelen cites with approval: "One should not undertake activities about which there is scientific uncertainty about their impact." Following this precept, scientific uncertainty about the safety of a genetically modified organism would mandate that it not be released.

In the end, of course, one cannot prove that a given undesirable outcome will never happen; one cannot prove a negative. The final decision about the release of any genetically engineered organism "will always be a political and ethical one." Hopefully, the expected costs and benefits will be assessed rationally with the help of risk analysis, and the opinions of the public will be taken into account. But van Dommelen emphasizes that the soundness of the political decision will be directly affected by the soundness of the scientific data deriving from the sets of relevant questions.

Van Dommelen offers additional advice. He suggests that the vested interests of industry raise serious concerns about the quality of data and relevance of any potential research questions provided by commercial sources: "The high political stakes and industrial interests surrounding the development of genetic engineering are certainly an 'excellent' context for the strategic use of a scientific guise for political claims on biosafety." Industrial developers of these organisms therefore might be asked to fund research by others rather than offer their own evaluation of the hazards. (Throughout the book, the author seems to assume that

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the biotechnology industry will be the only group wanting to release genetically modified organisms.) Van Dommelen holds that the "product versus process" controversy is artificial—a well-designed set of research questions will lead to consideration of both product and process. He argues that one should not make safety decisions based on analogies or on "familiarity" (with the properties of the organism and the environment into which it might be introduced) because these concepts are too imprecise to trust for decisions of safety. But on the other hand, analogies can be used to conclude that hazards might exist, and the familiarity concept can be used to formulate needed research questions. Van Dommelen finds it worthwhile to demarcate science from "transscience." Transscience questions—research problems whose solution would require inordinate amounts of time, effort, or both, and therefore cannot realistically be answered by science—should be answered politically.

On the whole, van Dommelen's proposals merit serious consideration, at least if one accepts the need for stringent application of the much-disputed (and variously defined) precautionary principle. The SRQ approach is intended to leave no stone unturned regarding scientifically testable concerns about safety. Broader participation in establishing the lists of questions and in interpreting the results should, in theory, lead to wider acceptance of decisions to release transgenic organisms. And the author's proposals leave room for protocols to be simplified as scientific knowledge about the presence or absence of theoretical hazards is increased and refined.

But van Dommelen's suggestion that commercial applicants (presumably the "industrial interests") be prevented from submitting their own data is questionable. No one can do a better job of testing an organism than those who developed it and know it intimately. To deny commercial firms (for example, seed companies and their plant breeders) the opportunity, or challenge, to present their own data may be good for public relations but not for provision of appropriate information. Rather than arbitrarily assuming that applicants from industry are dishonest because of their commercial interests (similar to categorizing their honesty according to racial origin or religious faith), it would be more constructive to diligently ensure the accuracy of data from all participants in the decisions. Perhaps a special set of relevant questions could be devised to ensure honesty on the part of applicants from all sectors, private and public (including nonprofit public service organizations). Or currently existing international standards for good laboratory practices might be adapted for the evaluating applications for the release of transgenic organisms.

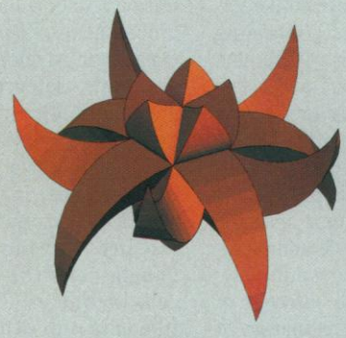
Whatever is done, one must recognize that the public sector and nonprofit organizations such as the International Agricultural Research Centers also are submitting, or intend to submit, applications for release of their own genetically modified organisms. They may resent being categorized at the same level of truthfulness—and with the consequent financial obligations—that van Dommelen suggests for the commercial institutions. Already, some of them express concern that proposed restrictions on release, some of which are intended to curb profit-driven industry, may hinder their charitable efforts to help the Third World poor by means of biotechnology.

Many fancy words have been written about genetically engineered organisms and their safety. Complicated terminology taken from science and philosophy ("the precautionary principle," for example) has been deployed to advance arguments on one side or the other. But beneath all the verbiage, the arguments are simply about how to find the right balance between two useful adages: "look before you leap" and "nothing ventured nothing gained." For the good of all, we must collectively decide when to pause and when to proceed in regard to genetically modified organisms. Based largely on fear of the unknown—not an unreasonable fear—we may incline more to the first adage than to the second. But we cannot agree on how far to lean, either now or in the future. Some parties do not lean at all; they are determined never to leap. But as far as I know, no one has concluded that we should leap with total abandon.

As van Dommelen says, arguments about how far to lean are too often disguised as scientific when in reality they are political. He carefully analyzes several examples in which zeal for release seems to have resulted in inadequate or even improper scientific analysis and recommendation. I would like to have also seen similar analyses of examples from the other side—cases in which determination to prevent or delay release has given rise to faulty science and recommendation. It would be instructive, for example, to read well-crafted analyses of the kind of warping that could result from anti-corporate or anti-American sentiments, as compared to the biases introduced by the urge to sell profitable new products.

Finally, van Dommelen gives little advice about risk analysis, except to say that it will not be contentious once parties agree on the nature of the hazards. One hopes he is right. Risk analysis will be the most essential part of every release decision because the precautionary principle prescribes the logical impossibility of proving the negative. Of course, one could simply follow this arbitrarily chosen principle to its logical end and never release anything. But then why construct the sets of relevant questions?

Despite its omissions and the biases it reflects, van Dommelen's book gives useful advice about ways to develop trustworthy protocols for identifying hazards associated with agricultural biotechnology. Implementation of the author's recommendations might give rise to wider agreement among scientists on the validity of release decisions made by regulatory bodies concerned with biosafety. But would such agreement influence the test-plot destroyers? Van Dommelen himself observes, "the larger biotechnology debate ... is riddled with ideological, ethical, and other normative evaluations.... [As] history keeps teaching us, ideology and world view will not easily be influenced by the results of scientific research."



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BROWSINGS

Graphica 1: The World of *Mathematica* Graphics. The Imaginary Made Real: The Art of Michael Trott. *John Bonadies, Ed.* Wolfram Media, Champaign, IL, 1999 (distributor, A. K. Peters, Natick, MA). 103 pp. $34.95. ISBN 1-56881-106-3.

Michael Trott uses Mathematica software to create a gallery of intricate and vibrantly colored images. Some play with geometric forms; others interpret functions, algorithms, and data from mathematics and physics. This construction of rotated and resized faces of an icosahedron (above) is among the simplest objects in the volume.

References

1. Speech at the National Press Club, Washington, DC. 13 July 1999.
2. *Agenda 21: Programme of Action for Sustainable Development*, United Nations Conference on Environment and Development, Rio de Janeiro, Brazil, June, 1992, p. 10.