The Philosophical Perplexities and Ethical Enigmas of Biotechnology: an Examination of the Regulatory Process in the United States

Paul C. Jepson
Integrated Plant Protection Center
Oregon State University
Corvallis, OR

My theme—"philosophical perplexities and ethical enigmas" associated with biotechnology—evolved from the *Ideas Matter* lecture series of the same name (http://oregonstate.edu/Dept/philosophy/ideas/biotech/), held at Oregon State University (OSU) in 2001 and 2002, and the 63rd Annual Biology Colloquium *Plant Improvement in the Genomic Age* at OSU in 2002. These events focused the attention of scientists engaged in biotechnological research on the wide array of ethical issues that surround the development and adoption of novel biotechnologies. The lack of resolution of many of these issues emerged as a persistent theme of both events, as did the responsibility of scientists to acknowledge and explore the ethical questions that underlie application of the discoveries that they make in this new and significant technology.

Ethics and Biotechnology

The ethics that underlie biotechnology are an important component of public concerns about genetically modified crops. These include concerns about the environment, human health, consumer rights and labeling, concerns targeted towards the poor and excluded, and arguments concerning sustainable, and what is viewed as "industrial," agriculture (Conway, 2000).

Ethical issues impinge on the debate surrounding genetically modified crops in a number of ways. These issues, progressing from the general to the more specific, include:

1. The value of international declarations of human rights as a possible basis for developing an ethical approach to the adoption of biotechnology globally.
2. The ethical standing of the environment and of non-human life in the development of these arguments.
3. The value of ethics in resolving the trade-offs between the environmental, economic and social costs and benefits of biotechnology.
4. The ethical responsibilities of corporations with respect to the development and introduction of biotechnology.
5. The role of ethics in the development and implementation of regulatory procedures that reflect societal values.

The most thorough analysis of ethics associated with biotechnology was undertaken by the FAO Panel of Eminent Experts on Ethics in Food and Agriculture (FAO, 2001). This analysis, which largely addressed the first three issues above, defined a set of core ethical standards, built from the International Declaration of Human Rights, and the current practices of the agency with respect to conservation and sustainable management of natural resources for present and future generations. Issue 4 is hotly debated beyond the realm of science, but Issue 5, concerning ethical responsibilities associated with the regulatory process, remains notably unaddressed.

Discussions about regulatory affairs often fail to move beyond highly technical arguments associated with specific tests or requirements. Regulations and their enforcement, however, provide the mechanism through which societal values confront the attributes and properties of new technologies, and determine whether they are acceptable.

MON 863 Corn and the EPA

In my verbal presentation, I applied an ethical perspective to the regulation of biotechnology by examining one facet of recent regulatory activity, *viz*. the review of impacts of transgenic corn expressing an insecticidal protein derived from a bacterium, on non-target organisms [specifically, *Bacillus thuringiensis* (*Bt*) Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR13L) in event MON 863 corn]. I reviewed data submitted by the registrant, preliminary evaluations by the EPA, and guidance on those evaluations provided by a FIFRA Scientific Advisory Panel (SAP) in August 2002 (EPA, 2002). A new conditional registration process has been issued by the EPA (2003). The basic ethical considerations underlying the regulatory process could be stated as follows (the author's list):

- Regulatory processes provide an opportunity to apply societal standards to an evaluation of the risks and benefits associated with a novel technology.

  The regulatory agency has a duty to develop procedures that reflect societal concerns, to adhere to published protocols and regulatory requirements, and to exhibit high standards of professionalism.
- Regulatory processes should promote human health and well-being and serve to advance beneficial technologies.
- Regulatory processes should help provide access by society to the benefits of technology.

  They should also serve to avoid suppression of other beneficial technologies.
- Regulatory processes should serve to protect the environment, defend biodiversity and to promote sustainable and productive agriculture.
- To achieve the above, regulatory agencies should apply current scientific standards.

In reviewing the data submission by the registrant in the case referred to above, and EPA's initial evaluation, the August 2002 FIFRA SAP expressed a number of concerns (EPA, 2002). Briefly, these included:

- The recommendations by EPA to the registrant regarding single-species testing were not considered appropriate.
- Field evaluation was not considered by the panel to be a substitute for tier-1 risk-assessment testing.
- The data reviewed by the panel did not support the EPA statement that MON 863 resulted in less impact on non-target invertebrates than conventional pest-management practices.
- The panel asserted that 3 to 4 years of experimentation were needed for field-based risk assessment.
- The protocol for tests on the lacewing, *Chrysoperla carnea* (Chrysopidae) was considered to be inadequate.
- A need was defined for development of acceptable standards for the design and conduct of laboratory studies.

In its conditional registration of protein Cry3Bb1 in corn event MON 863, the EPA (2003) included a number of additional requirements for the registrant. Those referring to non-target organisms included (condition 8) a requirement to submit laboratory tests for *Orius insidiosus*, a carabid beetle, and *Tetraopes* spp. (the red milkweed beetle), and (condition 9) a requirement for full-scale field or semi-field tests, including requirements to submit intermediate and multi-year results with stated statistical power, and to submit the final results to studies previously summarized in the submission reviewed by EPA and the FIFRA SAP.

An analysis of this process, based upon the general ethical considerations underlying the regulation of biotechnology, given above, concluded that EPA could adhere to these general ethical standards, and the expectations of society for an effective regulatory process by:

- Setting standards for an acceptable test design in *revised test guidelines* that acknowledge the recommendations of technical experts, and FIFRA SAPs (*i.e.* development of test guidelines that reflect current scientific standards).
- Improving the standard of evaluation, noting particularly the criteria for evaluating laboratory and field derived data, outlined by the FIFRA SAP.
- Rejecting tests that do not meet acceptable standards, rather than accepting them with the evident flaws within them.
- Withholding registration until acceptable tests are submitted, rather than submitting conditional registrations.

The benefits of adopting these recommendations for the EPA, and for society as a whole include the following:

- Moving beyond the *status quo* provides an incentive for registrants to submit packages that meet higher scientific standards.
- Improved guidelines would distribute the benefits of FIFRA-SAP guidance to subsequent submissions, and avoid having to repeat criticisms of the current process.
- EPA decisions would be based on clearer, more transparent criteria, and less upon "expectations" or variable expert judgment.
- An updated and revised process would provide a clear basis for rejection of submissions.
- An enhanced system would improve the credibility of EPA regulatory decisions in the international arena.
- Advances in the regulatory process would be consistent with the ethical responsibilities of the EPA towards society.

Conclusion

The ethical context for regulatory affairs, outlined in this analysis requires first and foremost that the highest standards are met by the regulatory agency on behalf of the society in whose interests it acts. Regulatory requirements and protocols must evolve with science and experience if the regulatory agency is to maintain the public trust and credibility in national and international debates surrounding biotechnology. In general, new agricultural technologies are not subjected to the kind of ethical scrutiny outlined by the FAO in its recent analysis. Regulatory requirements can be tuned to address some of these concerns, and, by doing so, could help resolve a debate that feeds upon the uncertainties surrounding these new technologies.

References

Conway GR (2000) Crop biotechnology: benefits, risks and ownership. Presented at GM Food Safety: Facts, Uncertainties, and Assessment; The Organization For Economic Co-Operation And Development (OECD) Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods, March 28, 2000. http://www.agbioworld.org/biotech_info/articles/conwayspeech.html.

EPA (2002) SAP Minutes No. 2002-05 FIFRA Scientific Advisory Panel Meeting, August 27-29, 2002. A Set of Issues Being Considered by the Environmental Protection Agency Regarding: Corn Rootworm Plant-incorporated Protectant Non-target Insect and Insect Resistance Management Issues. Minutes transmitted November 6, 2002. http://www.epa.gov/oscpmont/sap/2002/ index.htm.

EPA (2003) *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON 863 Corn. New PIP Active Ingredient Registration, Publication Number 730-F-03-01, issued March 6, 2003. http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_006484. htm.

FAO (2001) Report of the Panel of Eminent Experts on Ethics in Food and Agriculture. Rome: Food and Agriculture Organization of the United Nations. ISBN 92-5-104558-5. http://www.fao.org/DOCREP/003/X9600E/X9600E00.HTM.