

THE LAST WORD/

THE FREEDOM TO KNOW AND THE RIGHT TO DECIDE

by John H. Barton

Largely without oversight mechanisms, genetically engineered organisms have been field-tested in developing nations: the Wistar Foundation (Philadelphia, PA) vaccine was released controversially in Argentina while transgenic tomatoes came out more quietly in Mexico. Other projects await regulations: transgenic rices will soon be ready for field-testing; and the United States Agency for International Development (USAID) wants to test its rindpest vaccine in East Africa.

Two recent documents address this issue: the United Nations Industrial Development Organization's (UNIDO) "Voluntary Code of Conduct for the Release of Organisms into the Environment" and UNCED's (United Nations Conference on Environment and Development) "Environmentally Sound Management of Biotechnology: Background and Issues." The reports are important steps. As international documents, they have a special legitimacy. Even if not formally binding, they can be cited against a company that has little concern for its actions and can be mechanisms of pressure on the developing nation that is uninterested in adequate regulation.

However, they are not enough. They leave at least three important tasks for the international community: expanding the scientific base necessary for responsible decision-making; devising practical mechanisms for case-by-case judgment in developing nations; and building the mechanisms of public participation needed to sustain the long-term use of biotechnology.

Ecological Underpinning

The ecosystems in developed nations are typically quite different from those in developing nations. As centers of crop origin, tropical ecosystems are much more likely than temperate regions to contain wild relatives of transgenic crops. The soil flora are also distinct. Therefore, unlike much pharmaceutical safety evaluation, developing nation regulatory bodies cannot reasonably rely on prior decisions in developed nations.

The UNCED document calls for further work on the implications for release into differing environments and on potential long-term effects of the introduction of new transgenic organisms. The U.N. Environmental Program (UNEP, Nairobi, Kenya), the World Health Organization (WHO, Geneva, Switzerland) and the Organisation Internationale des Epizootiques are already either supporting or organizing some of the necessary research. But we need more: the area deserves significant public sector support.

Seeking Advice

Case-by-case review is currently essential to the evaluation of releases of genetically engineered organisms. But how can that work for developing countries?

Perhaps each should build and apply its own regulatory capability. India is doing so, and Mexico and Brazil are considering it. The approach has advantages—particularly, that it permits adaptation to the local regulatory traditions—which are often radically different from those of the source nation. But the option is available, at most, to a few

developing nations—those with substantial scientific and regulatory resources. Moreover, the promulgation of divergent regulations in different nations imposes substantial burdens on experimenters.

Perhaps, then, the Third World should rely on the existing developed nation decision processes. Most of the public and private sector institutions that wish to test transgenic organisms in the developing world are based in the developed world and already subject to developed world regulation. The approach would rely, in effect, on the regulation of technology exports. One disadvantage, clearly, is that it would not address research and development based in developing nations. But a more important difficulty is that the approach is highly paternalistic. Implicitly, the developing nations would be abdicating to the developed nations. They would be treated as though they were unable to make their own decisions about these experiments. (Aware of this drawback, the UNCED proposal suggests a variant of this approach which puts the onus back on the importing country—that an exporting country should notify the importing country of any transaction in genetically engineered organisms.)

Is international decision-making a possible solution to this dilemma? Probably not. Very rarely will one nation trust others or the international community to make decisions that affect its environment or its people's health. Informal or unofficial copying of foreign decisions, yes: but a formal commitment to such copying in place of national decision-making, no. The international community can, however, help—by providing an *ad hoc* advisory committee to help developing nations make specific decisions. The legitimacy of such an approach arises both because the advice (and subsequent decision-making) is science-based, and because the advice is provided "on request." The virtue of the advisory route is that it can be established quickly. Its most notable drawback is that the advice will probably not be formally binding; however, few governments would reject any negative advice from such a group. Thus, this would seem to be the most effective approach available for nations that lack the resources to create domestic institutions.

Neighborhood Watch

It is frequently noted that developing nations' laws governing the environment are excellent, but that their enforcement is non-existent. In such a context, enforcement depends critically on the availability of a domestic environmental movement concerned with and ready to publicize ill-conceived government or private actions. Public participation can provide a follow-through that the government often lacks. Both the UNIDO Code of Conduct and the UNCED proposal call for public hearings. They are absolutely right; this is an essential part of any case-by-case review process.

John H. Barton is George E. Osborne Professor of Law, Stanford Law School, Stanford University, Stanford, CA 94305-5015, U.S. These opinions are the author's own, and are not necessarily those of Bio/Technology.