REGULATORY CONCERNS AFFECTING DEVELOPING NATIONS

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An emerging goal of international agricultural crop research centers is to integrate biotechnology into established breeding programs—to enhance the efficiency of those programs and to devise new crop improvement strategies as quickly as possible. Breeding programs by their very nature require field-testing. Special trials are often necessary to screen for *in vitro*-derived traits. Many perennial crops take several years to mature, which means monitoring multiple flowering and fruiting cycles. Germplasm or cultivar development requires successive generations of breeding and testing to achieve agronomic fitness with stable expression of selected traits. This includes international trials and advanced testing in national programs required to evaluate material in multiple locations and environments.

Thus, the debate—much of it gratuitous—on the safety of using genetically engineered organisms in the environment has particular meaning to international agricultural development programs. Many countries are striving to construct appropriate biosafety regulations. In April, the Organization for Economic Cooperation and Development (OECD) convened a meeting of its "Group of National Experts on Safety in Biotechnology." They have placed a high priority on establishing a committee to develop "good developmental practices" for small-scale field-testing, with specific criteria for organisms requiring only minimal oversight—the low-risk category.

The developing world has received little attention in this regard, with the exception of this April's AID-sponsored international conference and last December's UNIDO/UNEP/WHO working party. These meetings have at least stimulated discussions—and even recommendations—on international regulatory dilemmas. The UNIDO/UNEP/WHO recommends developing global biosafety guidelines where they do not already exist—guidelines to cover the industrial, environmental, and agricultural applications of natural and genetically modified organisms. While developing such guidance, general principles established at the national and international levels should be considered.

Regulatory concerns in the developing world are complicated by the diverse interests and needs of the players: there are the governments and research institutes of the developing countries themselves; there are international agricultural research centers supported by donor agencies; there are research institutions and private industry in industrialized nations; and—as always—there are environmental and public advocacy groups. Each of these factions has its own agenda and its own definition of what constitutes safe and appropriate release.

Superimposed on the changing patterns of national regulations are the considerations of international funding agencies—which are heavily influenced by the regulatory climates of their own countries. International agricultural research centers are in an especially sensitive and important position because they operate in numerous countries, where they often benefit from a special status while being supported by a heterogeneous mixture of donors. Both donors and the international centers need to re-evaluate how using and importing introduced biologics affects their relations with the host country.

These complications are only made worse when it comes time for experimental-scale field-testing. Research scientists may confront a confusing array of national regulations. And, if regulations are not in place, U.S. funding agencies may require that such research be conducted under the same standards and regulations expected in the U.S.

We feel that biosafety concerns for regulating new technologies can be addressed through existing regulatory structures and agencies, starting with interdisciplinary institutional biosafety committees.

Concerns regarding the use of genetically modified organisms should be based on the unique properties of the organism itself, the nature of the environment in which the release will occur, and the type of testing required. Although there is a growing consensus that there are no hazards unique to genetic engineering or to gene transfer between unrelated organisms, this does not minimize the need to determine appropriate environmental precautions.

Selected institutions in developing countries should enhance their genetic engineering skills and be able to provide relevant "good developmental practices" and biosafety standards for planned release—be it contained testing or restricted and large-scale trials. Safety assessment is an integral part of research, and needs to be developed on a case-by-case basis. Formal risk assessment should be reserved for those cases in which there is scientific evidence of hazardous end-points. Likewise, establishing risk categories will help facilitate decision making. It will expedite regulatory procedures for low-risk organisms, while providing more restrictive guidelines for testing those at higher risk.

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