

Biosafety regulations

SIR — David Dickson's article (*Nature* 377, 94; 1995) on international regulatory agreements for genetically engineered organisms needs to be placed in context.

The international biosafety regulations being promoted by environmental regulators in the Netherlands, the United Kingdom and the European Union have some serious disadvantages. They would require case-by-case risk analysis by governments of field trials with genetically manipulated organisms (GMOs) that are largely of minimal intrinsic risk. The regulations would require new bureaucracies, as well as vastly increased costs to both governments and researchers. Under this scheme, organisms that are phenotypically identical to one another would be subject to significantly different regulatory requirements, determined solely by the method of genetic modification used.

The presumption that GMOs as a class of organisms are inherently dangerous has been exhaustively addressed — and discredited. The scope of GMO-specific approaches is incompatible with the broad scientific consensus, cited in an earlier leading article in *Nature* (356, 1–2;

1992), that “no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes”. The OECD's Group of National Experts on Biotechnology, the US National Academy of Sciences and its research arm, the National Research Council, as well as other groups, have reached similar conclusions.

Beyond wasting human and financial resources, misguided approaches to regulation may increase the vulnerability of developing countries. For example, while the approach of the European Union and the United Nations Environment Programme focuses exclusively on organisms manipulated by molecular techniques, non-indigenous organisms (“exotics”) that are not GMOs are exempt. Introducing into a domestic agricultural ecosystem new organisms that have evolved in completely different ecosystems may well pose a greater risk than introducing organisms created through genetic modification of existing domestic germplasm.

Rational approaches to the testing and use of new agricultural products by developing nations is critical for addressing two kinds of danger. First, regulatory disincentives can threaten continued increases in local food supplies by dis-

couraging research and innovation in agricultural biotechnology. Second, the unregulated introduction of non-indigenous organisms poses a genuine and serious threat to the diversity of developing countries. What is needed are scientific and risk-based regulatory policies that will protect the environment and encourage, not impede, sustainable development.

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