COMMENTARY

RISK ASSESSMENT

The protocol's illusionary principle

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In an editorial last month, this journal pointed out that the biosafety protocol recently completed in Montreal "violates a cardinal principal of regulation—namely, that the degree of scrutiny should be commensurate with risk." We think it important to examine in a bit more detail the antiscientific, if nonetheless increasingly popular, basis on which this deeply flawed protocol was conceived.

The protocol is founded on a "precautionary approach" to regulation, as described in the 1992 Rio Declaration on Environment and Development: ". . .lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The precautionary approach and precautionary principle are neologisms coined by opponents of technology who wish to rationalize banning things they don't like, such as gene splicing, cellular phones, oil exploration, and carbon dioxide emissions. This bogus "principle" dictates that every new technology must be *proven* safe before it can be used. An ounce of prevention is certainly desirable, but because nothing can be proved totally safe—at least, not to the standard demanded by antitechnology extremists—the precautionary principle creates prodigious obstacles to the development of new products.

Consider, for example, that bizarre speculations by activists about weather patterns being altered by a frost damage-mitigating "ice minus" *Pseudomonas syringae* bacterium once caused the US Environmental Protection Agency (EPA; Washington, DC) to delay approving a small-scale field trial of the microorganism. Precaution, in this sense, shifts the burden of proof from the regulator, who once had to demonstrate that a new technology was likely to cause some harm, to the innovator, who now must demonstrate that the technology will not. Regulatory bodies are free to arbitrarily require any amount and kind of testing they wish. Perhaps the finest—and certainly the most significant—post-Montreal example of the arbitrary and capricious application of the precautionary principle to agbiotech was the decision by the German government in February to block the commercial-scale cultivation of *Bt*-corn by the biotechnology company Novartis. This action came one day before it was expected to be approved for commercaial use by the Ministry of Agriculture, which specifically cited the need to respect the precautionary principle and called for more research into the crop plant's potential hazards.

Thus, rather than creating a uniform, predictable, and scientifically sound framework for effectively managing legitimate risks, the biosafety protocol establishes an ill-defined global regulatory process that permits overly risk-averse regulators to hide behind the precautionary principle in delaying or deferring approvals. Witness the regulatory feeding frenzy spawned by unscientific approaches to biotechnology regulation in Europe and at the US EPA. The result has been the virtual disappearance of gene-spliced foods from the shelves of European markets, hindrance of agbiotech research at US universities, and the near-elimination of once highly touted research on microbial pesticides and bioremediation.

Focusing mainly on the possibility that new products may pose theoretical risks, the precautionary principle ignores very real, existing risks that could be mitigated or eliminated by those products. If the precautionary principle had been applied decades ago to innovations like polio vaccines and antibiotics, regulators might have prevented occasionally serious side effects by delaying or denying approval of those products, but that precaution would have come at the expense of millions of lives lost to infectious diseases. Instead of demanding assurance of safety that approaches absolute certainty, the goal should be to balance the risk of accepting new products too quickly (Type I error in the parlance of risk assessment) against the risks of delaying or foregoing new technologies (Type II error). And because individuals' tolerance for risk is so heterogeneous, regulators should be open to the exercise of greater informed choice by the end users of technology.

More than one billion people in the world now live on less than a dollar a day, and hundreds of millions are severely malnourished. By increasing the efficiency of agriculture and food production, recombinant DNA technology can significantly increase the availability and nutritional value of foods and reduce their cost. But the application of the precautionary principle will stall progress and exact a substantial human toll. The huge stakes both in human and commercial terms demand that within the flawed regulatory paradigm agreed upon in Montreal, regulators create scientifically sound, risk-based frameworks for the regulation of recombinant organisms.

The seeds of risk-based regulation can be found within the biosafety protocol agreement itself. Annex II contains a guide to what the protocol considers adequate risk assessment. It properly focuses on the biological characteristics of the individual products, but leaves much discretion to regulators about the framework for risk analysis. Therefore, risk analysis of recombinant DNA-manipulated (and other) organisms could be conducted within a methodological framework that depends on the stratification of organisms into risk categories according to the consensus judgments of independent scientific experts.

One example of this approach has already been described[1]. A workshop conducted by the authors of that paper and attended by agricultural experts from six nations demonstrates that such risk categorization is feasible. In that exercise, the criteria used in the stratification included pathogenicity, invasiveness, possibility of impact on wild gene pools, weediness, center of origin, and risk to humans. Most of the crop plants evaluated were found to be in the "negligible risk" category (therefore requiring little or no regulatory oversight), and the rest were in the "low but nonnegligible risk" category (which might require only notification to a regulatory authority or a minimal safety review).

The advantages of this methodology are that it is highly flexible and that it may be used by regulatory bodies with various functions and philosophies of risk. Because the majority of organisms subject to the protocol will be plants, and most of these will be of negligible risk, this risk-based approach obviates the need for unnecessary or extensive case-by-case review and thereby eliminates an important source of regulatory disincentives to the use of recombinant DNA techniques for agriculture.

Although a risk-based review mechanism of this type would be an important first step toward scientific risk analysis, an oversight system should also include incentives to reward optimal decision making and should hold regulators accountable for both Type I and Type II errors. Although even the most carefully crafted institutional reforms cannot guarantee optimal risk assessment and risk management, formal institutional recognition that there is a trade-off between moving too quickly and too slowly can help to achieve net risk reduction and to promote overall social benefit.

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1. Barton, J., Crandon, J, Kennedy, D. & Miller, H.I. *Nat. Biotechnol.* **15**, 845–848 (1997).