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Correspondence
Nature Biotechnology
345 Park Avenue South
New York, NY 10010-1707, USA
or sent by e-mail to biotech@natureny.com
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The precautionary principle

To the editor:

In their commentary on page 360 of the April issue, Henry Miller and Gregory Conko declare that they wish to examine in more detail what they call the antiscientific basis on which the biosafety protocol was conceived. This they unfortunately fail to do. All we get is a list of epithets—deeply flawed, neologism, bogus. The precautionary principle is apparently the work of "antitechnology extremists" who wish to ban just about everything. This is, to use the authors' phrase, deeply flawed reasoning, if it can indeed be called reasoning.

The authors are skilled in the art of risk assessment. This is an art in which scientific knowledge is put into equations used to try to assess the risks associated with the use of various technologies, but it is not a predictive science. The arguments of risk analyzers cannot be said to be "more scientific" than the arguments of anyone else. Risk, stated most simply, is probability multiplied by consequences. In the field of biotechnology, it may be a useful measure of where we stand and give us a basis for discussion. As Miller and Conko note, risk assessment could be carried out according to the consensus of independent scientific experts. Do they mean independent from each other? A good start, perhaps, but what is needed is the judgment of scientists who stand completely free from the biotechnology industry. Can scientists who are closely involved with the industry be expected to perceive all the risks? Can they be perceived by the public as being unbiased? Tax-funded research institutes, standing totally free of the biotechnology industry, are urgently needed.

Anne Geddes Shalit
Project Leader
Department of Biology
University of Karlstad
Sweden

To the editor:

Miller and Conko's commentary (*Nat. Biotechnol.* **18**, 360, 2000) criticizes the Cartagena Protocol on Biosafety for the following operative provision implementing the precautionary principle: "lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism (LMO) on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the LMO ... in order to avoid or minimize such potential adverse effects[1]."

Consequently, decision making may take into account scientific uncertainty on a case-by-case basis: The Party of import can approve, with or without conditions, or prohibit the import. Except in a case in which consent is unconditional, a decision shall set out the reasons on which it is based. Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the LMO in the receiving environment.

The particular relevance to risk management is highlighted by a recent communication from the European Commission[2] seeking to establish guidelines for applying the precautionary principle beyond biosafety. Where action is deemed necessary, measures should be (1) proportional to the chosen level of protection, (2) nondiscriminatory in their application, (3) consistent with similar measures already taken, (4) based on an examination of the potential benefits and costs of action or lack of action, (5) subject to review, in the light of new scientific data, and (6) capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment. In conclusion, adequate handling of the precautionary principle outlined in the biosafety protocol could contribute to a well-balanced mechanism for the transboundary movement of LMOs.

Bernhard Jank
Institute of Applied Microbiology
University of Agriculture
Nussdorfer Lände 11
A-1190 Vienna, Austria
(Jank@edv2.boku.ac.at)
Johannes Rath
Institute of Zoology
University of Vienna,
Althanstrasse 14
A-1090 Vienna, Austria

1. *Cartagena Protocol on Biosafety* (http://www.biodiv.org/biosafe/BIOSAFETY-PROTOCOL.htm).
2. *Communication from the Commission on the precautionary principle* (http://www.europa.eu.int/comm/off/com/health_consumer/precaution.htm)

Henry Miller and Gregory Conko reply:

It has been said that an economist is someone who sees something work in practice and studies whether it could possibly work in theory. Jank and Rath and Shalit have, in effect, done the opposite: In spite of compelling evidence that the precautionary principle is being applied in a way that flies in the face of scientific principles and common sense—to the widespread detriment of consumers and commerce—they try to portray it as a neutral premise on which to base risk analysis and management. All technologies have risks and benefits, both demonstrated and hypothetical, but the precautionary principle stipulates that hypothetical risks should take precedence over substantive demonstrated benefits.

They suggest further that such documents as the European Commission's communication on the precautionary principle[1] will ensure "proportional," "nondiscriminatory," and "consistent" risk management practices that carefully weigh "potential benefits and costs" and that are "subject to review in the light of new scientific data." While we wish this were the case, real-world application of the precautionary principle has demonstrated that the concept remains a tool of politics, not science.

Consider the example we described. In February, the German government specifically cited the precautionary principle when it banned on the commercial growth of a *Bt*-maize variety a single day before the Agriculture Ministry's Office for Varieties was expected to announce its approval[2]. The German Central Commission for Biological Safety, a scientific group advising the government on genetic engineering, announced subsequently that the government had ignored the commission's recommendation for approval and that the commission "could perceive no scientific basis for the decision"[3].

As a tool of public policy, the primary shortcoming of the precautionary principle is that it incorporates neither coherent evidentiary standards nor any clear stopping points. As we argued in our original essay, it effectively frees regulators to arbitrarily require any amount and kind of testing they wish; likewise, it permits them to ignore overwhelming evidence of a product's (or a technology's) safety and to prevent its use.

Shalit also argues that "the workings of the free market do not provide a broad enough context" in which to evaluate biotechnology products. But whatever the inadequacies and pitfalls of the market, those of regulatory politics—where true accountability is even more rare and hidden, self-interested agendas are the rule—are far greater. In any case, the primary thrust of our commentary was to suggest mechanisms intended to promote science-based risk analysis. As it is currently applied, the precautionary principle does not.

1. European Commission. *Communication from the commission on the precautionary principle.* (communication) Brussels, 2 February, (2000) 1.
2. Abbott, A. Germany holds up cultivation of GM maize. *Nature* **403**, 821 (2000).
3. Hodgson, J. The advisory committee strikes back. *Nat. Biotechnol.* **18**, 476 (2000).