By Henry I. Miller

Politics and Cynicism Dominate UN Biotech Deliberations

U.S. negotiators win a round, but not on principle

Biotechnology regulator-wannabes around the world were dealt a blow last February at negotiations held in Cartagena, Colombia, under the mandate of the 1992 United Nations Convention on Biological Diversity. There, a small bloc led by the United States rejected a proposed international regulation advocated by more than 130 countries.

That is excellent news of a sort, because the proposed regulation—a UN biosafety protocol (bsp) to regulate the testing of and trade in gene-spliced organisms, seeds, and perhaps products derived from them—is unscientific, anti-innovative and anticompetitive. bsp would regulate organisms simply because they are crafted by sophisticated molecular techniques that are not inherently riskier than less-advanced methods of gene transfer. In anything resembling its present form, bsp would be harmful to consumers, harmful to the environment, and catastrophic for international research on ways to improve agricultural productivity.

The bad news from Cartagena is that the U.S.-led bloc (which includes Canada, Australia, Chile, Argentina, and Uruguay) won only a temporary victory. Worse, U.S. negotiators did the right thing for the wrong reasons and now find themselves in an untenable position. Although they could have argued persuasively that the proposed regulation lacks scientific and common sense, their arguments, calculated to protect large agribusiness interests, instead focused on trade considerations. The U.S. negotiators' position is undermined by the fact that the biotech regulatory policies of the United States (as well as the proposed bsp) flagrantly violate the General Agreement on Tariffs and Trade (gatt), which governs world trade. I discuss that issue below.

There is nothing mysterious about the new biotechnology; it is an extension of techniques that have been developed and applied over the centuries. The scientific community has long understood the relative risks of using rdna to improve the genetics of animals, microorganisms, and plants. In 1987, the National Academy of Sciences (nas) concluded that:

- There is no evidence of unique hazards either in the use of gene splicing techniques or in the movement of genes between unrelated organisms.
- The risks associated with the introduction of gene-spliced organisms into the environment are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods.
- The risks associated with introducing a gene-spliced organism into the environment depend on the nature of the organism and of the environment into which it is to be introduced, not on the method of engineering the organism.

The National Research Council (nrc), the research arm of nas, concluded in a 1989 report 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," whether in the laboratory, in the field, or in large-scale environmental introductions. nrc drew on extensive observations of experiences with plant breeding, the introduction of genetically modified plants, and the introduction of genetically modified microorganisms. For example, the nrc report described pre-gene splicing hybridizations in which whole chromosomes were moved from one species or genus to another, across natural breeding barriers. Such "wide crosses" have yielded many genetically improved plant varieties—including potato, tomato, wheat, corn, oat, and pumpkin—that Europeans and Americans consume routinely and safely.

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nrc emphasized the greater control and power afforded by molecular techniques: "Recombinant dna methodology makes it possible to introduce pieces of dna, consisting of either single or multiple genes, that can be defined in function and even in nucleotide sequence. With classical techniques of gene transfer, a variable number of genes can be transferred, the number depending on the mechanism of transfer; but predicting the precise number or the traits that have been transferred is difficult, and we cannot always predict the phenotypic expression that will result. With organisms modified by molecular methods, we are in a better, if not perfect, position to predict the phenotypic expression."

Such conclusions have clear regulatory implications: recombinant organisms and products derived from them should be treated no differently than other products or organisms, except as scientific considerations may dictate. The use of molecular methods of gene transfer does not, in itself, warrant regulatory action. In the words of the authoritative October 1993 report of the UK House of Lords Select Committee on Science and Technology: "As a matter of principle, [gene-spliced]-derived products should be regulated according to the same criteria as any other product."

In that regard, it is noteworthy that governments generally do not require pre-market regulation of new varieties of agricultural plants or microorganisms, except those that are known pests or pathogens or that may harbor agents harmful to plants or animals. (The same principle determines whether a government declares certain organisms subject to quarantine upon importation.) Such largely laissez faire policies encourage the voluntary testing of new plant varieties by plant breeders, other researchers, and manufacturers of food and agricultural products. The proposed UN regulation would introduce draconian rules—but only for products improved with the most precise and sophisticated techniques.

bsp would make gene-spliced organisms more expensive to test, produce, and use. Experience in the United States indicates that the costs of field testing such plants would be 10 to 20 times greater than the costs of field testing plants having identical properties but modified with older, less-precise techniques. According to a U.S. Department of Agriculture study, the prices of wheat and coarse grains (corn, barley, and sorghum) could increase worldwide by an average of 2 percent and 5.6 percent, respectively, if bsp were fully implemented. Developing countries would be the main victims of the proposed regulation: they would have to spend more for food and would be unable to acquire the new technology.

Paradoxically, almost all developing countries favor restrictive biotech regulation. The environmental regulators in those countries see biotech regulation as a growth industry, and they have been bought off by the promise of resources for "capacity building" (a UN euphemism for bigger regulatory bureaucracies).

During the negotiations in Cartagena, disagreement focused on the degree to which various economic interests would be disadvantaged by bsp. Rafe Pomerance, deputy assistant secretary of state and head U.S. negotiator, said that the United States had made many concessions but that the talks broke down because "there were two compromises we were not prepared to make. One is to tie up trade … [and] the second is to allow this regime, without a lot of deliberation, to undermine the [World Trade Organization] trading regime." In other words, the United States and its allies would be willing to tolerate onerous case-by-case review of research involving innocuous genetically improved plants—a catastrophic outcome for academics and small companies—as long as the producers of large commodity crops are not affected. The U.S. government is prepared to export its collaboration with big agribusiness by using over-regulation to keep entrepreneurial biotech companies and seed producers out of international markets.

Conspicuously absent from the negotiations was any mention of the debilitating scientific deficiencies of bsp. Why? Because biotech regulation at three U.S. agencies—the Environmental Protection Agency, Department of Agriculture, and Food and Drug Administration—is similar to the proposed UN regulation: in one way or another, all three agencies focus on gene-spliced organisms. Pomerance's strategic problem is that the technique-based approach to domestic regulation has been roundly and consistently condemned by the scientific community—and any regulation that is not scientifically supportable is a non-tariff barrier to trade, a prima facie violation of gatt. Most U.S. (as well as European and Asian) regulation is unscientific and therefore illegal under gatt.

The U.S. negotiators at Cartagena were in fact arguing against the very kind of regulation imposed by U.S. government agencies at home. Apparently, the U.S. government really favors discriminatory, excessive regulation—but not where it threatens the interests of major U.S.-based agribusinesses.

When the negotiations resume sometime before May 2000, they will continue to be based on politics, expediency, and perceived narrow self-interest, rather than on scientific principles, actual risks, and the public interest. What will surely emerge is a regulation that is less objectionable to the United States, its allies, and big agribusiness, but one devoid of scientific and common sense. The result will violate the principle that something that isn't worth doing at all isn't worth doing well.

Instead of lending a hand to the UN effort, the United States should long ago have taken the scientific and moral high ground by insisting that: (1) any regulation aimed only at gene-spliced organisms is wholly unacceptable and (2) any UN agency or program associated with such a regime, directly or indirectly, cannot be funded from U.S. dues. ■