ENVIRONMENTAL RELEASE: THE BATTLES AND THE WAR ON TWO FRONTS

by Richard D. Godown

Deciding how best to regulate the environmental release of genetically engineered organisms has proven to be a thorny—and controversial—issue. Neither the United States nor the European Community (EC) has successfully addressed all the points. We haven't won the war, but in the U.S., at least, we've won a lot of battles. The Environmental Protection Agency has reviewed and approved a wide variety of field research applications. And the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has developed sound guidelines for regulating genetically engineered plants and plant pests. In the two years these APHIS regulations have been in effect, over four dozen genetically engineered plants have been successfully field tested. We should see the first plant products on the market in the next three years.

But where is the EC heading? Earlier this year, the European Parliament deliberated on coupled directives regarding the manufacturing and release to the environment of genetically engineered organisms. The contained use directive (as originally proposed by the EC Commission in Brussels) emerged relatively unscathed from the EC deliberations: that directive was passed by the Council of Ministers in June (see *Bio/Technology* **7**:742, Aug. '89). Unfortunately, the same cannot be said of the environmental release directive.

The Committee on the Environment, Public Health, and Consumer Protection appended no less than 50 amendments onto the EC Commission's original proposal. To be sure, many of these amendments were cosmetic. Others, however, would have effectively brought research to a standstill, not allowing any environmental release "...unless it is proven and verified to have no negative impact on the environment and humans [Amendment 9]"—an impossible burden of proof. And Amendment 32 would have limited release to situations "...where it has been demonstrated that the organisms in question are recoverable" for a five-year period. This latter provision was defeated by only one vote in the full parliament—which, with only 26 percent of its members present, was hardly full. The remainder of the 518 members were busy campaigning for reelection. The EC ministers did not approve the environmental release directive, but referred it back to committee for further debate.

There is another difference between the two directives. The contained use directive will set the framework for regulating manufacturing processes. If the ultimate regulations are too onerous, companies will end up manufacturing off-shore and exporting their products back into the EC. On the other hand—unfortunately—the environmental release directorate will lead specifically to product-based regulations. Genetically engineered plants and microorganisms destined for agricultural use would then have to meet any regulatory standard established by the EC and its member countries.

Any biotechnology company developing products for environmental applications has had to contend with the fact that there is a degree of scientific uncertainty involved. But they also know that this uncertainty is contingent on the nature of the host organism and the foreign DNA it carries. No one who has studied this issue would argue with the statement that genetically modified microorganisms pose more uncertainty than their plant counterparts, nor should it be argued that the uncertainty is one not susceptible to scientific evaluation and reasonable control. Any regulatory framework needs to be flexible enough to relax the degree of oversight as more data warrant it. It is unclear whether the emerging EC environmental regulations will have this flexibility.

Obviously, U.S. biotech companies would prefer that international regulations be harmonized. Not only would this ensure orderly product development, but it would also allow data acquired outside the EC to support product approval in EC member countries.

If the final EC regulations are drastic, and stricter than those elsewhere, there will be two closely linked outcomes. For one, companies may reconsider developing products for EC markets. The more significant impact, however, will be on EC agricultural policies. If biotechnology is able to lower farm input costs and generate alternative agriculturally derived products as projected, the EC will find itself in the position of increasing subsidies to its agricultural community. This will adversely impact farmers and consumers alike—not to mention the effect on international trade. The recent multilateral debates on whether farm subsidies are in fact non-tariff trade barriers have been contentious—and unresolved. (The United States has proposed that all farm subsidies be phased out.)

It is imperative that all of us interested in the future of biotechnology take a broader view of both research and regulatory developments. An orderly regulatory process that recognizes the benefits and seeks to minimize the risks is in everyone's best interest. We certainly see this evolving in the United States. Should we not expect the same within the European Community?

Richard D. Godown is the president of the Industrial Biotechnology Association, 1625 K Street, N.W., Washington, DC 20006. These opinions are the author's own and do not necessarily reflect those of *Bio/Technology*.