THE LAST WORD

by Joseph G. Perpich

EXPORT CONTROLS ON BIOTECHNOLOGY

The future of regulations governing export of biotechnological processes and products remains unclear. Congress, the courts, and the executive branch are reviewing all existing federal research and regulatory policies for biotechnology covering industrial applications in health, agriculture, chemicals and the environment. Export controls will become one very important part of this regulatory review. And these controls—whatever they may be—will strongly influence the industry and, perhaps, academia.

Two factors drive the move for export regulation: the possibility of biotechnological warfare and the prospect of well-coordinated foreign competition.

The Department of Defense (DoD) claims considerable evidence that the Soviet Union is using genetic engineering technology for offensive biological warfare, violating the Biological Weapons Convention of 1972. Accordingly, the purpose of Defense export guidelines is to restrain exports that could help potential adversaries wage offensive (or defensive) chemical or biological warfare. Defense has included certain biotechnologies on its Militarily Critical Technologies List. Fermentation technology and high-capacity separatory devices are high on this list.

And then there are the commercial considerations underlying Department of Commerce (DoC) initiatives. Japan, for example, has targeted biotechnology for industrial development and, through its Ministry of International Trade and Industry, is coordinating the resources of Japanese companies.

Thus, for reasons of commerce and national security, DoC is likely to issue draft biotechnology export regulations in 1985. Biotechnology industry representatives have recommended creation of a technical committee to advise Commerce (and the Defense and State Departments) on biotechnology export regulations. Under the Export Administration Act, the DoC is authorized to create such committees, and such an advisory mechanism must be created before export regulations are drafted. Such a committee should ask which controls are, in fact, feasible for recombinant organisms, host-vector systems, and bioprocess systems. This effort must include review of Commerce's Commodities Control List and its relevant sections specifying the organisms that may be exported without a license. The number of microorganisms exempted from licensing requirements must be expanded to include, for example, organisms of particular industrial importance.

The advisory committee should also identify the main problems that follow any effort to control technology export. Currently, the government is applying export laws to technological data as well as to products. Unfortunately, the boundary dividing basic research (which is exempt from the Act) from transfer of technological data (which falls under the regulations) is not yet clearly defined. Yet it is in precisely this area that discussion among government, academic, and industrial policymakers is most necessary.

Last year, for example, the DoD announced plans for creating a category of Defense-supported research, unclassified but "sensitive," for which permission for publication would rest exclusively with the Department. The Commerce Department also drafted export regulations restricting publication of research related to technologies included on the Militarily Critical Technologies List. Universities in both cases were able to obtain revisions in these regulations that would largely exempt research from publication review by the Defense and Commerce Departments. A recent Harvard University report says, however, that other federal agencies and departments are inserting pre-publication review clauses in university contracts for unclassified research.

If the policies developed by Commerce and Defense on university-based research are implemented successfully, then biotechnology research at universities should also be exempt from DoD restrictions and export controls. And now may be the opportune time to try to obtain policy agreements for industrial R&D.

Concern over federal regulation of industrial R&D is strong and the National Academy of Sciences is commissioning a panel to look further into export controls and industrial research. Such a panel might provide a framework for developing government policies to govern industrial research.

What else can be done? I would urge the Cabinet Council biotechnology working group established last year and chaired by George A. Keyworth, the President's Science Advisor, to turn its attention to future export regulations governing biotechnology products and processes. (The working group, on December 31, issued a report recommending new administrative mechanisms for oversight and regulation of biotechnology, but the report did not address export controls.) In addition, organizations such as the Industrial Biotechnology Association, the Chemical Manufacturers Association, and the Pharmaceutical Manufacturers Association should consider supporting the National Academy of Sciences study of industrial biotechnology—in light of export controls developed for other high technology industries. These organizations should also keep members informed of all Congressional and Administration developments in the reauthorization of the Export Administration Act, whose authority expired in 1983. For now, the Act's authority has been extended by the President.

The policy debate over legislative and regulatory export control initiatives will be intense over the next two years, and the biotechnology industry will participate. The biotechnology industry—and the academic community—must work with the government to ensure biotechnology export rules based on legitimate commercial and national security interests, rules that do not harm international exchanges upon which our industrial and academic community so vitally depend.

Joseph G. Perpich, M.D., J.D., is vice president for planning and development of Meloy Laboratories, Inc., Revlon Health Care Group, Springfield, VA. These opinions are the author's own, and are not necessarily those of *Bio/Technology*.