ASSOCIATION UPDATE

TRADE ASSOCIATION SETS 1989 PRIORITIES

NEW YORK—The Industrial Biotechnology Association (IBA, Washington, D.C.) announced in late October that the U.S. Patent and Trademark Office (PTO) would, as a result of IBA's efforts, address the biotechnology patent backlog (*Bio/Technology* 6:1367, Dec. '88). This demonstrated a successful coordination between industry and government. In 1989, however, biotechnology faces critical legislative and regulatory issues not likely to be solved so easily. An animal patent moratorium bill expected out of Congress, along with the recent draft of biotechnology regulations out of the Environmental Protection Agency (EPA, see "Proposed EPA Rules Go Another Round," in this issue) are among the most significant and worrisome topics.

IBA president Richard Godown anticipates that the first biotech initiative will be to wrestle with a revived version of the Transgenic Animals Patent Reform Act. Introduced in 1988 by Rep. Robert Kastenmeier (D-Wis.), the bill passed the House but died in the Senate Judiciary Committee. Most troublesome to biotech was the provision that would have changed patent law so that farmers would not have to pay the inventors of genetically-engineered, patented farm animals when they use or sell the offspring.

Godown called the Kastenmeier bill "entirely unacceptable to IBA...The farm exception is too broad." IBA quietly has begun a dialogue with farm groups in an attempt to reach a politically viable accommodation, but Godown wonders whether the public uproar on this issue—drawing in animal rights groups and right-to-life activists—will allow for a reasonable discussion. "To date," he explains, "the level has been purely emotional and nonscientific."

Also of concern is the bill introduced in the Senate on the next-to-last day of the 100th Congress by Max Baucas (D-Mont.). The Novel Organism Release Act would amend the Toxic Substances Control Act (TSCA) to call for issuance of permits for testing and distributing novel organisms. "This is more restrictive than the current premanufacturing notice required by TSCA," says Godown. "This bill needs to either die or change."

IBA has gone on record with the EPA that the current draft rules under TSCA as applied to biotech would dramatically shift federal regulatory policies. These include significant new use notices pre-release for commercial products not specifically excluded, and establishing local biosafety committees. "IBA does not believe the present draft is ready for publication in the *Federal Register* as a proposed rule. Its umbrella approach is inconsistent with our emerging regulatory experience for both contained and field use of biotechnology products," according to Godown.

As for IBA's activities at the other regulatory agencies, Godown applauds legislation calling for more examiners at the Food and Drug Administration (FDA). IBA's preference is to accomplish this through a budgetary allowance—which comes out of general revenues—as opposed to user fees. The rationale is that drug review and approval serves the public generally, not just industry.

—Mark Ratner