EDITORIAL CORRESPONDENCE:
BIO/TECHNOLOGY, 65 Bleecker St., New York, NY 10012. Telephone: (212) 477-9600. Telex: 668497UW.
BIO/TECHNOLOGY, 4 Little Essex Street, London WC2R 3LF. Telephone: (01) 836 6633. Telex: 262024.

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A CRAZY QUILT TO COVER BIOTECH

The patchwork presented by the U.S. Office of Science and Technology Policy (OSTP) as its "Proposal for a Coordinated Framework for Regulation of Biotechnology" is an ungainly creature. The authors have cobbled up a matrix of existing statutes that might conceivably cover biotechnology, and called them "ample authority" for the task.

At first glance, this ugly duckling of a regulatory proposal seems unlikely to win any particular admiration, especially from a community that has been subdued in its praise of the government's actions on biotechnology to date—the fitful attempts to curb exports of products, equipment, and information, or the cutbacks in research funding, for example.

Yet there is something perversely pleasing about an attempt to apply a patchwork of law to a crazy quilt of an industry. And while a coherent, custom-made regulatory code appeals to one's sense of order, the very diversity of the biotechnology industries threatens to subvert any attempt to classify, categorize, or codify from scratch.

Those viewing biotechnology from the outside tend to confuse the bag with its contents. The name is misleading: it seems to imply that the biotechnology industries share something more substantial than a state of mind and a common interest in regulations. (There is something circular in this reasoning: biotechnology appears as a single entity only because it fears regulation by those who assume it is a single entity.) Anyone who thinks that biotechnology is a tidy, close-knit discipline need only edit a publication for the whole community to discover his or her error.

Shall biotechnology grind to a halt while Washington tries to figure out what biotechnology is, why it might be dangerous (to our health, our wealth, or our morals), and what it must do to serve us best? The January conference of the Brookings Institution (see this month's *Dateline*) addressed these questions. Yet on the closing day, a long-time advisor to E.F. Hutton (which owns the copyright on the term itself), chided the conferees for using "biotechnology" interchangeably with words like "bioengineering," "bioscience," "biomedical research," and a host of others. The United States will be a long time asking these questions and, if it does the job right, an even longer time turning the answers into laws—laws that will regulate the biotechnology industries, not strangle them or give them free rein.

For the present, at least, the regulations proposed by OSTP have some signal virtues. The laws are on the books now, and we can begin to act on that basis now. These regulations depend on familiar laws administered by familiar agencies; they permit those agencies to build on their accumulated knowledge of the pharmaceutical, chemical, agricultural, and other industries. And many of the regulations endorsed by OSTP rely heavily on case-by-case review. Until we develop definitions and goals precise enough to produce broad, consistent formulas, the trained judgments of scientists and laymen are the best defense against accident.

While we cannot agree that the proposal is, as Congressman James Florio (D-NJ) has called it, "a sham, and a dangerous sham at that," it does have some weaknesses that will keep it from providing the ultimate solution to the regulatory dilemma. There is, as Jonathan Lash of the Natural Resources Defense Council points out, a gap in the existing regulations between the phases of research and marketing: some provision must be made for making non-pharmaceutical products. The OSTP's regulatory Matrix depends for much of its authority on bills that are facing reauthorization; without these acts, gaping holes open in the net. And, reauthorized or not, no statute can be effective if the government will not spend the money to enforce it. In biotechnology, especially, basic research is a key part of that effort.

—Douglas McCormick