"A MUTABLE FEAST"

FOOD PROPOSALS FOR FDA TO SAVOR

WASHINGTON, D.C.—Early this year, U.S. Food and Drug Administration (FDA, Bethesda, MD) Commissioner David Kessler promised that the agency would, by the end of 1991, present proposals for regulating foods produced using biotechnology. However, in a move that figuratively mixes the notions of "fast" and "all natural" foods, the Environmental Defense Fund (EDF, New York) last month called on FDA to adopt three regulatory provisions that EDF says are in the "interests of both consumers and the biotechnology industry." The proposals apparently signal that EDF and other public-interest organizations are devoting increased attention to food and agricultural uses of biotechnology.

EDF's Rebecca Goldburg assails FDA for "failing in the last five years to come up with any regulations for genetically engineered foods" and thus "dropping the ball" on matters of public safety. Meanwhile, she adds, "Consumers should not be guinea pigs for untested food substances." According to her colleague, attorney Doug Hopkins, EDF is "proposing three reasonable, common-sense regulations to protect consumers." The proposals—and the legal and scientific rationale behind them—are outlined in a 74-page booklet, "A Mutable Feast: Assuring Food Safety in the Era of Genetic Engineering." In brief, the three proposals call on FDA to:

- Subject new substances in genetically engineered organisms used for food to the premarket safety-testing requirements applicable to food additives;
- Require detailed labeling for foods containing genetically engineered ingredients or whose characteristics were changed by the use of genetic engineering;
- Require manufacturers to notify the agency of the composition of all genetically engineered foods at least 90 days before they are marketed.

EDF is not the only group to offer proposals to FDA for regulating genetically engineered foods. Last year the International Food Biotechnology Council (IFBC, Washington, DC) issued a 400-page report that focused on plants and microbes and recommended "no additional regulatory measures" for genetically engineered food products. The IFBC report, which was endorsed by biotechnology industry groups, concluded that "existing laws and practices" provide a suitable framework for assessing risks (*Bio/Technology* 8:822, Sept. '90). EDF, by contrast, urges that key FDA statutes be amended to make explicit several key interpretations. Perhaps most importantly, EDF argues that because the expression of engineered genes in foods is novel, it should trigger regulatory scrutiny under the 1958 Food Additives Amendment to the Food, Drug, and Cosmetic Act.

The IFBC report seemed to have little visible impact following its release. However, Michael Taylor, who was involved in its preparation while working in the private sector, is now FDA's deputy commissioner for policy. Just how FDA officials will use it or the new EDF report is not clear. Some officials dismiss the "mutable feast" as "sophistry," arguing that its interpretations of pertinent statutes are "one sided" and, thus, misleading.

However, other FDA officials say the EDF report is "useful" and that its legal analysis is at least "consistent" with some doctrines set forth in several laws concerning food safety. Nonetheless, they criticize the report for going "too far" on some regulatory matters but "not far enough" on others. For example, EDF calls for regulating essentially all genetically engineered foods. But the agency generally does not subject whole foods to regulatory scrutiny under the additive statute; instead they usually are considered safe unless "adulterated," says Eric Flamm from the agency's Office of Biotechnology.

The EDF report recommends strict product labeling as an alert to genetic engineering being involved in a food product. The suggestion makes both industry representatives and FDA officials uncomfortable. As an alternative, the IFBC report called upon manufacturers to notify the agency voluntarily about significant manufacturing procedures. FDA, for its part, is leaning toward a more comprehensive rule in which manufacturers are subject to inspections and to notifying the agency of production changes, says an official.

"The EDF document is one more piece of the puzzle," says FDA's James Maryanski, who is helping to draft the agency policy. "We start with the premise that there are not inherent hazards, but we want a mechanism to ensure the new is as safe as the old. There are a lot of options. And the issues outlined in the EDF report are options we're looking at. The real job now is developing our policy statement." —**Jeffrey L. Fox**