BY RUSS HOYLE

# EATING BIOTECHNOLOGY

*"There is presently no general scientific basis for presuming that foods from organisms into which new substances have been genetically engineered will be safe for human consumption."*

—Environmental Defense Fund

If sophistry were a felony, the author of that statement would be locked up.

Is the value to consumers of bioengineered food worth the possible hazards they imagine it may present to their health? The U.S. Food and Drug Administration (FDA, Bethesda, MD) has formulated an answer to that question in long-awaited guidelines on genetically engineered food, and it is a resounding "yes." "There is no evidence of unique hazards associated with rDNA technology," according to a study on which FDA based its policy. "Potential risks that may occur in food manufacture are the same kind as those associated with conventional methods." The announcement of the biotech guidelines, which reportedly have the approval of the White House and are due out imminently, is likely to coincide with a surge of publicity for Calgene's (Davis, CA) new bioengineered super tomatoes, slated for arrival on U.S. vegetable stands next year.

**New FDA policy**

The new FDA policy, which lays out key components of FDA's regulatory "road maps" for transgenic plants, is the result of extensive research by the International Food Biotechnology Council (IFBC, Washington, DC), a consortium of academic and private-sector scientists set up in 1988. The IFBC's peer-reviewed findings were published 18 months ago in the journal *Regulatory Toxicology and Pharmacology* (**12**: No. 3, Dec., 1990). The list of 26 companies that participated reads like a Who's Who of the food biotech industry. It includes Calgene, BioTechnica International (Overland Park, KS), Campbell Soup (Camden, NJ), DNA Plant Technology (Cinnaminson, NJ), DuPont (Wilmington, DE), and Monsanto (St. Louis, MO).

From the beginning, however, the real star of the show has been Calgene's FLAVR-SAVR super tomato. Calgene uses anti-sense RNA technology to suppress the gene for polygalacturonase, an enzyme that causes softening and spoilage. The new tomato has been field tested for four years and is widely acknowledged to be safe for human consumption. Since Calgene's tomatoes will remain firm for a week or so longer than normal tomatoes, they may be transported to market after fully ripening on the vine, resulting in a more flavorful "summer" tomato all year round. In short, the super tomato is tailor-made to convince the public that biotech food is safe as spinach. The stakes are high. The U.S. retail market for fresh tomatoes is reportedly worth in excess of $5 billion a year. "The defining feature," says Calgene President Roger Salquist, "is that it will produce direct benefits for the consumer."

**Regulatory guidance**

If all goes according to script, the FDA policy initiative should pay off handsomely, at least in the short term, by providing the biotechnology industry with critical regulatory guidance at a time when a number of other genetically engineered food products are in the pipeline for marketing, from oilseed products like canola oil to pest-resistant soybeans. In keeping with the Administration's new biotech scope policy, bioengineered whole food products would not receive special treatment under current FDA food regulations. Translation: it is up to industry researchers to ferret out potentially harmful recombinant foods and subject them to tough scrutiny as food additives.

That should raise a red flag for the biotech industry. Can the makers of genetically engineered food really expect FDA—the folks who brought us unregulated silicone breast implants—to assure the public that their products are safe for human consumption? The bottom line—one with which the 1990 IFBC report concurs—is that without the kind of backlog of experience that anchors most judgments about food safety, the behavior of some natural toxins, hormones, and pesticides in new untried genetically engineered configurations may well be difficult to predict and possibly harmful.

The IFBC report takes the position that the risk is scientifically manageable and that industry has the technical capacity to monitor itself. Moreover, industry spokespersons like Calgene's Salquist point out that extensive market research indicates "no evidence" of undue public fear about bioengineered food. Salquist also claims that a more Draconian regulatory regime would force Calgene and other biotech food companies to "abandon the field and apply our science elsewhere."

**L-tryptophan debacle**

An alternative proposal, submitted to FDA by the Environmental Defense Fund (EDF, New York), an environmental group, calls for regulating biotechnology products under stringent food-additive statutes and strict labeling standards. Much of the ambivalence of its authors is due to the troubling case of Showa Denko's (Tokyo) L-tryptophan, the unregulated, genetically engineered nutritional supplement that caused some 27 deaths from eosinophilia-myalgia syndrome (EMS) in the late 1980s. FDA, despite an ongoing investigation into the causes of the EMS outbreak, has maintained a studied silence about the episode, which has been traced back to changes in a bacterial fermentation process involving a recombinant strain of *Bacillus amyloliquefaciens*. Critics charge that FDA's silence has led to an unwarranted public perception that the EMS outbreak had nothing to do with genetic engineering *per se*, a conclusion that thus far is unproven. In fact, an FDA official confirms that whatever changes occurred in the Japanese company's fateful October 1988 fermentation batch are still unknown. The agency, insists the official, is determined to get to the bottom of the case and publish the results in a proper forum.

The emerging biotech food industry would be wise to insist upon seeing the final, peer-reviewed FDA account of the L-tryptophan mess—or seeing a clear, unambiguous signal from the American public that it is ready to consume bioengineered whole foods, no questions asked—before committing itself to the path of least regulatory resistance proposed under the new FDA policy guidelines. Under the circumstances, a public commitment to thorough science—and a more cautious approach to market psychology—would seem a small price to pay, considering the potential rewards.