LABELING GENETICALLY ENGINEERED FOODS

NEW-FOOD RULES

MIAMI—Both the Commission of the European Communities (EC, Brussels, Belgium) and the U.S. Food and Drug Administration (FDA, Bethesda, MD) will bring out major new proposals on novel-food legislation in the next few weeks, and neither has ruled out absolutely the labeling of genetically engineered foods as a matter of course. Yet representatives of both bodies, speaking at a regulatory roundtable at this year's Miami Bio/Technology Winter Symposium here, hinted strongly that such labeling would not be required. "The likelihood is very low," said Henry Miller, director of the FDA's Office of Biotechnology. "Labeling needs to be accurate and convey material information, and the use of a particular technique is often not material information."

To illustrate the point, Miller discussed hypothetical products in which the Brazil-nut storage protein—an allergen for some people—was transferred into potatoes or tomatoes to increase their protein quality: while the presence of the protein would be material information, the method by which it got there (expression of genes transferred by genetic engineering) would not.

FDA's policy statement, expected to be complete in March or April and to appear as part of a larger notice from the Biotechnology Working Party of the President's Council on Competitiveness, will map out both the types of new foods on which the agency would like to have information and which forms of regulatory submissions would be appropriate.

The corresponding European proposals for a directive on novel foods are expected to emerge a month or two before those of the FDA. On labeling, Paul Gray, an EC senior adviser, agreed with Miller that labeling was only necessary if there was "something substantial to be informed about." The EC proposals, however, will contain specific provisions on labeling—probably more as a safeguard against misleading naming of products than as a way of forcing manufactures to divulge information on the processes used in manufacture.

Like the proposals from FDA, those from the EC are directed at all novel foods, not specifically at those in which biotechnology is involved. Yet as proposed, the EC proposals would channel all foods either obtained by biotechnological processing or containing "viable" genetically engineered components before a Community-wide, expert-approval body. The decision tree used to set the scope of the directive makes a clear distinction between foods from sources (plants, animals) altered by conventional breeding and those obtained by "genetic-modification techniques" (presumably meaning rDNA technology). While the former need to go before the expert-approval body only if the alteration to the source "significantly affects" nutritional value, digestion/metabolism, or the level of undesirable substances, all food products from genetically modified sources must be approved.

The exceptional treatment afforded to genetically engineered products can be explained, at least in part, by the continuing need for legislators in other EC directorates to pry particular product categories out from the legislation (known as DGXI) enacted by the Environmental Directorate-General: this covers the release of genetically engineered products not specifically regulated elsewhere. The stated aim of the EC is to provide a "one-key, one-door" regulatory system so that manufacturers need interact only with one agency for each product. As the EC's Gray noted, this has meant that the proposals for new European approval processes for pharmaceuticals, veterinary products, and pesticides have all had to incorporate provisions for environmental safety assessment.

—**John Hodgson**