FDA REGULATION OF FOOD PRODUCTS
DERIVED FROM GENETICALLY-ALTERED PLANTS

POINTS TO CONSIDER

1. FDA's objectives in regulating the food products of biotechnology should be to assure safety and provide assurance to the public that foods derived from modern biotechnology processes ("biotech foods") are being adequately regulated, while avoiding "unnecessary" regulatory processes, i.e., ones that do not justify the resource burdens they place on FDA and industry.

2. If the principle is followed that regulation of biotech foods should be grounded as much as possible in current law and practice regarding conventional foods, most categories of biotech foods will be regulated under the food additive/GRAS authority of the FDC Act. These include processed derivatives of whole foods, food processing enzymes and other biological ingredients, and biotech-derived functional chemical additives. For these categories, FDA will have its maximum authority, and it will be difficult for critics to contend that, in general, biotech foods are not being closely regulated by FDA.

3. Whole foods are a special and difficult case because there is no established pattern of affirmative FDA regulation but something is needed to assure safety and satisfy the public that it is being protected. For biotech whole foods, some regulatory middle ground is needed between complete reliance on an unamplified 402(a)(1) and routine imposition of the food additive/GRAS regime, with its requirement of petitions as the only basis for obtaining any FDA involvement in the task of safety assurance.

4. The two obvious options are (a) placing biotech whole foods in the food additive/GRAS category but building greater flexibility into the process of making determining, and informing FDA about independent GRAS determinations, and (b) leaving most biotech whole foods under 402(a)(1) but beefing up FDA's involvement in assuring compliance with 402(a)(1).

5. The food additive/GRAS option, if routine petitions are to be avoided, would require overt FDA affirmation of the concept of relying on independent GRAS determinations. It would also involve presumably promulgation of guidelines for making the safety evaluation and documenting it in a way sufficient to satisfy the "publication" requirement. To avoid the appearance of complete industry self-regulation, some process
short of a formal GRAS petition would have to be available for informing FDA about independent GRAS determinations.

Advantages of Food Additive/GRAS Option:

- Places biotech whole foods in the legal category that provides FDA greatest regulatory authority;
- Could be used to compel formal petitions on a routine basis.

Disadvantages of Food Additive/GRAS Option:

- Places biotech whole foods in a different regulatory category than conventional whole foods;
- Creates precedent that is difficult to reconcile with not regulating conventionally-altered whole foods in food additive/GRAS category, undermining concept of "food" as a regulatory category;
- Has the appearance of loosening requirements of an existing regulatory category to fit biotech foods;
- At odds with emerging FDA legal interpretations of what is required to achieve GRAS status, including "publication" requirement.

6. The 402(a)(1) option would involve promulgation of guidelines for evaluating the safety of whole foods and establishment of a process for notifying FDA of new products and the basis for judging them safe. It could also preserve the possibility of moving a biotech whole food to the food additive/GRAS category if it were determined, on the basis of criteria promulgated by FDA, that the genetic alteration made the composition of the food significantly different in ways that adversely affect safety or nutrition.

Advantages of the 402(a)(1) Option:

- Grounds regulation of biotech whole foods in current law and practice regarding conventionally-altered whole foods;
- Preserves FDA role of prescribing ground rules for safety evaluation and a mechanism for keeping informed about new products;
- Preserves option of shifting to food additive/GRAS category when facts warrant;
- Creates appearance of beefing up an existing regulatory category to handle biotech whole foods;
Disadvantages of 402(a)(1) Option:

- Could be criticized as less than the most rigorous regulatory category;
- Places somewhat greater legal burden of proof on FDA to enforce against wrongdoers.

7. Under either option, there are generic issues of safety evaluation that may require special, focused FDA attention if the regulatory process is to be efficient and credible. The best example is the marker gene issue. A relatively small number of marker gene systems will be used in a large number of biotech whole foods. It might be desirable for FDA to initiate its own regulatory process to identify the safe applications of the marker gene systems. This could be done under the general authority of section 402 and might or might not result in promulgation of a regulation. A starting point might be a call for data that could provide the basis for at least the beginning of a generic safety assessment.