VII C. Safety of Foods and Food Additives Developed by Biotechnology

The regulatory framework and the FDA approach to assessing the safety of foods developed by biotechnology is discussed by the Commissioner and presented in detail in the Agency's "Statement of Policy: Foods Derived from New Plant Varieties." (It should be noted that the agency's statement only pertains to foods derived from new plant varieties, including those developed through biotechnology; the policy does not address all food additives developed through biotechnology nor is it strictly limited to foods derived from new plants developed solely through biotechnology.)

The following information provides a summary of the safety assessment of foods derived from new varieties of plants, and the FDA's approach to non-clinical safety testing.

FDA's science-based approach for ensuring the safety of foods from new plant varieties focuses safety evaluations on the objective characteristics of the food: The safety of any newly introduced substances and any unintended increased concentrations of toxicants beyond the range of known to be safe in food or alterations of important nutrients that may occur as a result of genetic modification. Substances that have a safe history of use in food and substances that are substantially similar to such substances generally would not require extensive pre-market safety testing. Substances that raise safety concerns would be subjected to closer inquiry. This approach is both scientifically and legally sound and should be adequate to fully protect public health while not inhibiting innovation.¹

Figure 8 summarizes the safety assessment of new plant varieties.

The Agency's approach to non-clinical safety testing of foods and food additives derived from new plant varieties has also been described.¹

Animal feeding trials of foods derived from new plant varieties are not conducted routinely. However, in some cases testing may be needed to ensure safety. For example, substances with unusual functions or that will be new macronutrients of the diet may raise sufficient concern to warrant testing. Tests could include metabolic, toxicological, or digestibility studies, depending on the circumstances.

Developers may also need to conduct tests on the "wholesomeness" of foods derived from new plant varieties as a means of ensuring that the food does not actually contain high levels of unexpected, acutely toxic substances. Such tests may provide additional assurance to consumers that food developed by new technology is as safe as food derived from varieties already in their grocery stores. However, animal tests on whole foods, which are complex mixtures, present problems that are not associated with traditional animal toxicology tests designed to assess the safety of single chemicals. Potential toxicants are likely to occur at very low concentrations in the whole food, and the tests may therefore be inadequately sensitive to detect toxicants. Efforts to increase the amount of whole food ingested by the test animals in order to increase the sensitivity and attempt to establish a traditional margin of safety (for example, a 100-fold safety factor) may not always be possible. When tests are contemplated, careful attention should be paid to the test protocol, taking into account such issues as nutritional balance and sensitivity.¹

References

- 1. Kessler, D. A., Taylor, M. R., Maryanski, J. H., Flamm, E. L., and Kahl, L.S. (1992) The Safety of foods developed by biotechnology. *Science* 256:1747-1749 (&1832).
- 2. Anonymous (1992) Statement of Policy: Foods derived from new plant varieties. Fed. Reg. 57:22984.

Figure 8

Safety Assessment of New Yarieties: Summary

Unexpected Expected or or unintended intended effects effects Safety Safety Safety Safety assessment: new assessment: assessment: assessment: or modified introduced the host plant the donor(s) carbohydrates, proteins fats or oils Unusual or toxic Is food from Is food from components? **L**No donor commonly donor commonly Nutritional allergenic? allergenic? alterations? Changes in Yes Yes digestibility? Consult Consult No FDA FDA Yes Concerns due to Toxicants reported toxicity Consult Not in safe Yes) No 🏲 acceptable or biological FDA range? function? Νo No Yes Macroconstituent in the human or Yes Important Consult animal diet? nutrients within No ⊮ FDA range? Yes No-No concerns No concerns