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[1] and presented in detail in the Agency's "*Statement of Policy: Foods Derived from New Plant Varieties*."[2] (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.

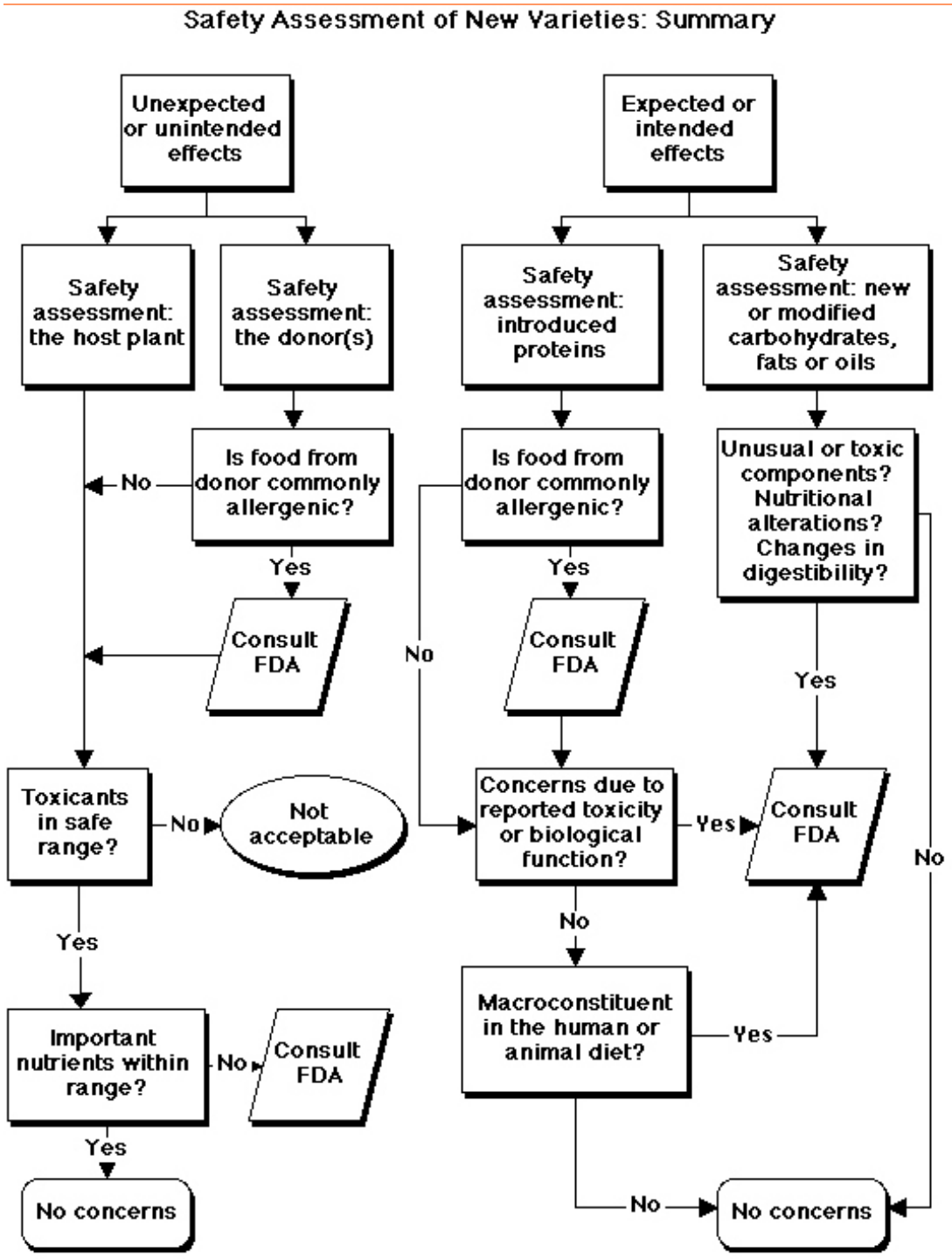
Developers may also need to conduct tests on the "wholesomeness" of foods derived from new plant varieties as a means of ensuring that the food does not actually contain high levels of unexpected, acutely toxic substances. Such tests may provide additional assurance to consumers that food developed by 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 Varieties: Summary
Unexpected or unintended effects
Expected or intended effects
Safety assessment: the host plant
Safety assessment: the donor(s)
Safety assessment: introduced proteins
Safety assessment: new or modified carbohydrates, fats or oils
Is food from donor commonly allergenic?
Is food from donor commonly allergenic?
Unusual or toxic components? Nutritional alterations? Changes in digestibility?
No
Yes
Yes
Yes
Consult FDA
Consult FDA
No
Toxicants in safe range?
No
Not acceptable
Concerns due to reported toxicity or biological function?
Yes
Consult FDA
No
Yes
Yes
No
Important nutrients within range?
No
Consult FDA
Macroconstituent in the human or animal diet?
Yes
Yes
No
No concerns
No
No concerns