

Memorandum

Dateaugust 15, 1991

From Chairman, FDA Task Group on Food Biotechnology, HFF-300

Subject Task Group on Food Biotechnology: Progress Report 2

To The Director, Center for Food Safety and Applied Nutrition, HFF-1

The FDA Task Group on Food Biotechnology has drafted a document on regulatory approaches available to the FDA for foods and feeds developed through biotechnology. The Task Group reviewed (1) types of new varieties of foods/feeds from plants, animals, and microorganisms; (2) safety issues and relative concern; and (3) regulatory options.

Four broad concerns were identified: (1) New substances for which safety basis is not established; (2) Unexpected changes in food/feed composition that result from genetic modification; (3) Labeling; and (4) Environmental issues.

The Task Group identified three regulatory options to address the concerns:

- Pre-market authority under the Food Additives Amendment;
- 2. Post-market authority under section 402(a)(1); or

3. New legislation.

The Task Group proposes the following regulatory approach:

(1) The Food Additives Amendment applies for all new varieties when foods/feeds become components of foods.

(2) An "Umbrella food additive regulation(s)" be promulgated to cover foods/feeds that contain substances for which safety can be established; foods/feeds outside the "umbrella" would require petitions.

(3) Unexpected changes would be covered primarily by good developmental and manufacturing practices and guidance from FDA.

(4) Labeling would be used to inform consumers about nutrient content, allergenic potential, changes of common/usual name of

products. (5) Environmental assessments for issues not previously addresses by other agencies would be required for petitions.

Suggested further work:

(1) Circulate Task Group paper for wider review in FDA;

(2) Assign scientific groups in CFSAN and CVM to develop criteria

for "umbrella" regulation(s);

(3) Draft a notification procedure to interpret the "umbrella";

(4) Draft "Points to Consider" guidance for foods/feeds from

plants, animals, and microorganisms; (5) Contract NRC for study on scientific criteria and consensus.

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