

Public Hearing on Foods Being  
Marketed as  
“Functional Foods” –  
Issues and Questions from the FR Notice

December 5, 2006

9am-4pm

FDA Wiley Building Auditorium



# Issues and Questions

- Issues 1-2 – Ingredients
- Issues 3-6 – Labeling
- Issue 7 – General



# Issues and Questions

- Issue 1: The CSPI petition requests that we require food companies to notify us regarding the use of "novel ingredients" prior to marketing foods containing such ingredients.



# Issues and Questions

- Question 1a. Is there a need for a regulatory definition and a distinct regulatory approach to the evaluation of the safety of ingredients added to "functional foods"? If yes, what would be included in this new definition and approach that is not adequately addressed under the existing definition of food additive or the provisions in the definition for GRAS substances, and what is the scientific and legal basis for your position? Under what legal authority could FDA create this new definition and distinct regulatory approach?



# Issues and Questions

- Question 1b. Should companies that market ingredients for addition to "functional foods" be required to notify us prior to introducing the ingredients into interstate commerce? If yes, what is the scientific and legal basis for your position?



# Issues and Questions

- Issue 2: Generally, food additives have been used in conventional foods for their technical effects on the food, not for their effects on the body. Now, the interest in various uses of certain ingredients in conventional foods is due to the marketing of these conventional foods as "functional foods" with claims about health benefits.



# Issues and Questions

- Question 2a. What types of data and information would be appropriate to demonstrate that ingredients added to conventional foods being marketed as "functional foods" meet the safety standard of "reasonable certainty of no harm"? What is the scientific and legal basis for your position?



# Issues and Questions

- Question 2b. How could we partner with interested stakeholders regarding the development of appropriate recommendations or other information regarding the safety assessment of ingredients added to "functional foods"?



# Issues and Questions

- Issue 3: The CSPI petition requests that we require food companies to notify us within 30 days of marketing a conventional food bearing a structure/function claim if such food contains a "novel ingredient," and to include the disclaimer currently required on dietary supplements making structure/function claims on the label and in labeling of such foods.



# Issues and Questions

- Question 3 - If our statutory authority permits, should we require food companies to notify us within 30 days of marketing a conventional food bearing a structure/function claim and to include the disclaimer currently required on dietary supplements making structure/function claims in labeling of such foods? If yes, what is the scientific (e.g., consumer studies) basis for your position? Under what existing legal authority could FDA require notification of these claims? Under what legal authority could FDA require inclusion of such a disclaimer with these claims?



# Issues and Questions

- Issue 4: The IFT report recommends that companies wishing to make label claims regarding the effects of "functional foods" or ingredients convene panels of independent experts qualified to evaluate the efficacy of the functional food component under consideration. According to IFT's recommendations, the findings of these Generally Recognized as Efficacious (GRAE) panels would be submitted to FDA under a process that is similar to the notification program that we proposed for GRAS substances.



# Issues and Questions

- Question 4. Within our statutory authority, how (if at all) should FDA utilize the findings of non-governmental groups, such as the IFT recommended GRAE panels, in support of health claims, nutrient content claims, and other labeling claims about the effects of a "functional food" or ingredient, such as structure/function claims? What is the scientific and legal basis for your position?



# Issues and Questions

- Question 4 (con't). Should FDA institute a premarket notification process for review of the scientific evidence for structure/function claims for "functional foods" and ingredients, as recommended by IFT? What is the scientific basis for your position? Under what existing legal authority could FDA institute a premarket notification process for review of the scientific evidence for "functional foods" and ingredients?



# Issues and Questions

- Issue 5. FDA has interpreted the court decision in *Nutrilab v. Schweiker* to limit structure/function claims for conventional foods to claims about effects that derive from the taste, aroma, or nutritive value of the food or food ingredient that is the subject of the claim. FDA's health claim regulations also require that the substance that is the subject of the claim contribute taste, aroma, nutritive value, or a technical effect recognized in FDA's food additive regulations



# Issues and Questions

- Issue 5 (con't). Because we recognize that food substances may confer health benefits through a number of processes, we have provided significant flexibility in determining whether a substance possesses nutritive value. Nutritive value is defined at 21 CFR 101.14(a)(3) as a value in sustaining human existence by such processes as promoting growth, replacing lost nutrients, or providing energy...



# Issues and Questions

- Issue 5 (con't). The IFT report criticizes the approach of requiring that the health benefit be derived from the food's nutritive value as too restrictive to allow for claims on foods being marketed as "functional foods." Instead, the IFT report recommends that FDA permit a labeling claim for a "functional food" if the claimed benefit is based either on nutritive value or on "the provision of a physical or physiological effect that has been scientifically documented or for which a substantial body of evidence exists for plausibility"



# Issues and Questions

- Question 5. Given the agency's interpretation of the definition of nutritive value as reflected in 21 CFR 101.14(a)(3) and our decisions on the health claims reviewed to date, does or will the agency's interpretation of *Nutrilab v. Schweiker* to limit structure/function claims and health claims to those that are based on nutritive value (or other food attributes such as taste and aroma) adequately allow for claims in the labeling of "functional foods"?



# Issues and Questions

- Question 5 (con't). If no, how is the agency's approach inadequate? What is the scientific and legal basis for your position? If you favor a change in the agency's approach, do you recommend that FDA adopt the IFT report's recommendation on this issue, or some other alternative? What legal rationale would support your preferred change in approach?



# Issues and Questions

- Issue 6: The IFT report recommends that research into "functional foods" be stimulated using incentives to the food industry, including market exclusivity for their bioactive food components and government research grants for the investigation of these components. There is currently no statutory provision for exclusivity of the use of a substance added to food or for the use of a health claim.



# Issues and Questions

- Question 6. Should FDA provide incentives to manufacturers to conduct further research on emerging substance/disease relationships? If yes, how? If yes, what is the scientific (e.g., consumer research) basis for your position? (For example, in the case of exclusivity, we are interested in consumer data concerning the use of a health claim on one product but not on other similar products by other manufacturers, and in how such data show that such claims are or are not misleading.) Under what existing legal authority could FDA provide such incentives?



# Issues and Questions

- Issue 7: The FDCA does not recognize "functional foods" as a distinct category of food, either by definition or through establishing specific requirements for "functional foods." The IFT report recommends that we establish, by regulation, a definition of, and labeling requirements for, "functional foods." The IFT report asserts that these regulations are necessary because consumer interest in the relationship between diet and health has increased the demand for these foods.



# Issues and Questions

- Issue 7 (con't). According to the IFT report, this increased consumer demand is causing the food industry to add more and larger amounts of substances to food and this competitive pressure has shifted the focus of food fortification from carefully orchestrated and closely monitored interventions for addressing specific dietary deficiencies to a focus on meeting market demands.



# Issues and Questions

- Question 7. Can the conventional foods being marketed (now or in the future) as "functional foods" be adequately addressed through the current regulations for food additives, GRAS substances, and labeling claims? If no, how are these regulations insufficient to address these products, and what is the scientific and legal basis for your position?



# Public Comments

- Speakers will be limited to 5 minutes each
- Speakers will be heard in the order in which they registered
- As the speaker before you is ending his or her comments, please begin making your way to the front of the auditorium.

