CORRESPONDENCE/

Food for Thought

To the editor:

Russ Hoyle's commentary, "Eating Biotechnology" (*Bio/Technology* **10**:629, June), discusses the Food and Drug Administration's (FDA) policy for foods derived from new plant varieties, but mischaracterizes our policy in several important aspects—possibly because at the time his article was prepared the policy guidelines were "due out imminently." Nevertheless, it is critical that FDA's policy be clearly understood by industry and the public, and I would like to correct any misconceptions regarding how our policy was developed.

Mr. Hoyle asserts that FDA's policy "is the result of extensive research by the International Food Biotechnology Council (IFBC)." In fact, our policy was developed by FDA scientists who considered a large number of scientific articles and reports as background material, including the IFBC report; the report of the Joint FAO/WHO Consultation, "Strategies for Assessing the Safety of Foods Produced by Biotechnology," WHO, Geneva (1991); the report, "A Mutable Feast: Assuring Food Safety in the Era of Genetic Engineering," Environmental Defense Fund, New York (1991); "Food and New Biotechnology—Novelty, Safety, and Control Aspects of Foods Made by New Biotechnology," (NORD, 91:18); the draft report, "Concepts and Principles Underpinning Safety Evaluations of Food Derived from Modern Biotechnology," Group of National Experts on Safety in Biotechnology, Organization of Economic Cooperation and Development; and "Approaches to Assuring the Safety of Crops Developed Through Wide-Cross Hybridization," Food Directorate Symposium, Ottawa, Canada (1989), to list a few examples.

In developing our policy, we evaluated the types of traits introduced into food crops currently undergoing field tests that have been developed using the newer techniques of biotechnology, primarily recombinant DNA techniques. These are the plants that are likely to be commercial food products in the foreseeable future. We thereby identified the following issues that are important for evaluating the safety of these foods: new substances introduced by gene transfer; potential for unintended toxicants; changes in important nutrients; and potential allergenic substances. These scientific issues are identified and discussed in many of the cited reports.

Mr. Hoyle also implies that our regulatory guidance is "the path of least regulatory resistance" that leaves "it up to industry to ferret out potentially harmful recombinant foods." To the contrary, the food additive provisions of the Federal Food, Drug, and Cosmetic Act require all substances intentionally introduced into food to undergo premarket approval if the substance is not generally recognized as safe (GRAS). Under our policy, all substances introduced by gene transfer are subject to this requirement unless there is a scientific basis for the exemption. (This is in contrast to the recommendation of the IFBC report that substances intended to affect agronomic characteristics of the plant be exempt from food additive regulation.) The reason that many substances introduced into foods by gene transfer may not require FDA approval as food additives is that they may be substances that already have a safe history of use in food (or are substantially similar to such substances) and would likely be GRAS. However, as is the case with chemicals added during food processing, substances that are different from substances in food or that raise safety questions must be approved by FDA before they may be used in food.

Further, the adulteration provisions of the law place a legally enforceable duty on producers to ensure that all foods they market are safe. Because of the potential consequences that may arise if FDA challenges a product on safety or legal grounds, producers routinely consult with the agency before introducing new products. FDA encourages such consultations and expects producers of foods derived from plants modified by new biotechnology to discuss any safety and regulatory issues for these products with the agency.

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Positively Luminescent

To the editor:

PROSAMO (Planned Release of Selected and Modified Organisms) is a three-year plant and microbial research programme operating as a partnership between the U.K. government (DTI), AFRC, industry (a consortium of ten major biotechnology companies), and four leading academic research laboratories. The overall goal of PROSAMO, which commenced in 1989, has been the assessment of risks associated with environmental introduction of genetically modified organisms (GMOs) to provide a safe and confident basis for development of GMO-related biotechnology.

This letter focuses on the microbial component of PROSAMO, where emphasis has been on the development and testing of novel methodologies for detection of genetically modified microorganisms essential for risk assessment.

The PROSAMO microbial programme involves collabo-