Food

Consultation Procedures under FDA's 1992 Statement of Policy - Foods Derived from New Plant Varieties

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Guidance on Consultation Procedures
Foods Derived From New Plant Varieties

Office of Premarket Approval*
Center for Food Safety and Applied Nutrition
and
Office of Surveillance and Compliance
Center for Veterinary Medicine
FOOD AND DRUG ADMINISTRATION
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This version supersedes the June, 1996 version. It has been revised to reflect reorganizations within the Office of Premarket Approval of the Center for Food Safety and Applied Nutrition, and the Center for Veterinary Medicine. This guidance document represents the agency's current thinking on consultation procedures regarding foods derived from new plant varieties. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

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I. Introduction

FDA recognized in its 1992 policy statement regarding foods derived from new plant varieties (May 29, 1992, 57 FR 22984) that it is prudent practice for developers of new varieties to consult with the agency on safety and regulatory questions, especially with regard to products developed through new technology. Because recombinant DNA (rDNA) technology (bioengineering) is advancing rapidly, FDA believes that it is in the best interests of the regulated industry and the agency for developers to inform FDA, as discussed below, prior to commercial distribution, about foods or feed derived from new plant varieties, including those derived using rDNA techniques.

FDA has received several inquiries from developers of bioengineered foods regarding the appropriate procedures for informing the agency about their market entry plans. In order to respond to these inquiries, FDA has developed this guidance document. The document describes 1) an approach through which developers can consult with the agency (Section II below), and 2) procedures by which the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) will process these consultations and bring them to closure (Section III below). These procedures may change as the agency gains more experience in dealing with foods derived from new plant varieties including those produced via bioengineering.

II. An Overview of the Consultation Process

The goal of the FDA's evaluation of information on new plant varieties provided by developers during the consultation process is to ensure that human food and animal feed safety issues or other regulatory issues (e.g. labeling) are resolved prior to commercial distribution. During the consultation process, the FDA does not conduct a comprehensive scientific review of data generated by the developer. Instead, the FDA considers, based on agency scientists' evaluation of the available information, whether any unresolved issues exist regarding the food derived from the new plant variety that would necessitate legal action by the agency if the product were introduced into commerce. Examples of unresolved issues may include, but are not limited to, significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, new allergens, or the presence in the food of an unapproved food additive. The FDA considers a consultation to be completed when all safety and regulatory issues are resolved. In 1994, the FDA discussed this consultation process during a public joint meeting of the agency's Food, and Veterinary Medicine Advisory Committees, which consist of food and feed safety experts from outside the agency. The committee members agreed with the FDA that, based on the types of bioengineered foods and feeds under development, the consultation procedures provide an appropriate level of government oversight.

A. Initial Consultations

The agency explained in the 1992 policy that consultations on new plant varieties are appropriate forums for industry and the agency to discuss scientific and regulatory issues prior to market entry. The agency continues to encourage developers to consult early in the development phase of their products, and as often as necessary. The agency believes that this is a prudent practice at this pioneering stage in the development of bioengineered foods. Such consultations will facilitate resolution of safety, nutritional, and regulatory issues. When one line derived from a transformation event has been shown to raise no such issues, the agency believes that it is unlikely that other lines generated from the event would raise issues that would be the subject of a consultation. However, should a line show characteristics that would raise safety or regulatory issues, the FDA encourages and would expect developers to consult with the agency to ensure that those issues are resolved prior to marketing.

B. Final Consultations

At some stage in the process of research and development, a firm will have accumulated the information that it believes is adequate to ensure that the product is safe and complies with the relevant provisions of the Food, Drug, and Cosmetic Act (the Act). The firm will then be in a position to conclude any ongoing consultation with FDA. The agency recommends that the developer take the following steps to inform FDA about bioengineered foods that are intended to be introduced into commercial distribution:

1. submit to FDA a summary of the safety and nutritional assessment that has been conducted (as described below); and
2. if necessary, meet with agency scientists (at headquarters or through a video- or teleconference, depending on the circumstances) to discuss the scientific data and information that support the summary of the safety and nutritional assessment. This meeting will allow scientists from the firm and FDA to discuss and clarify the data and information provided in the summary document. In some cases, a meeting may not be necessary if, for example, FDA scientists are sufficiently familiar with the firm's product, a firm submits adequate supporting information together with the summary, or a consultation involves a food derived from additional lines derived from the bioengineered line through traditional breeding.

The safety and nutritional assessment summary should contain sufficient information for agency scientists to understand the approach the firm has followed in identifying and addressing relevant issues. Such information would ordinarily include:

1. The name of the bioengineered food and the crop from which it is derived.
2. A description of the various applications or uses of the bioengineered food, including animal feed uses.
3. Information concerning the sources, identities, and functions of introduced genetic material.
4. Information on the purpose or intended technical effect of the modification, and its expected effect on the composition or characteristic properties of the food or feed.
5. Information concerning the identity and function of expression products encoded by the introduced genetic material, including an estimate of the concentration of any expression product in the bioengineered crop or food derived thereof.
6. Information regarding any known or suspected allergenicity and toxicity of expression products and the basis for concluding that foods containing the expression products can be safely consumed.
7. Information comparing the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties with special emphasis on important nutrients, and toxicants that occur naturally in the food.
8. A discussion of the available information that addresses whether the potential for the bioengineered food to induce an allergic response has been altered by the genetic modification.
9. Any other information relevant to the safety and nutritional assessment of the bioengineered food.

III. Consultation Procedures

A. The Biotechnology Evaluation Team

The Office of Premarket Approval (OPA) of the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Surveillance and Compliance (OSC) of the Center for Veterinary Medicine (CVM) have established a Biotechnology Evaluation Team (BET) to facilitate, and to ensure consistency in the process by which firms consult under the 1992 policy and inform FDA regarding the marketing of bioengineered foods and food ingredients derived from new plant varieties including those developed using rDNA techniques. The BET oversees the consultation process, identifies regulatory and scientific issues that need to be addressed, and once all relevant issues have been adequately addressed, brings the consultation to closure. The procedures described below represent procedures FDA expects to follow in most circumstances; however, deviations may result for cause.

The BET (core group) generally will be composed of a consumer safety officer (CSO), a molecular biologist, chemist, environmental scientist, and toxicologist from appropriate divisions within OPA/CFSAN, and a nutritionist from OSC/CVM. The CSO, from the Regulatory Policy Branch (RPB) of the Division of Product Policy (DPP) of OPA/CFSAN, will ordinarily chair the BET, except in cases where the bioengineered product has predominantly animal feed applications, in which case, a scientist from the Nutrition and Labeling Team (NLT) of the Division of Animal Feeds (DAF) of OSC/CVM will chair the team.

The core group may need to be supplemented with additional expertise on a case-by-case basis. For example, if a given consultation has labeling or infant formula issues, assistance will be sought from the Office of Food Labeling, and the Office of Special Nutritionals of CFSAN, respectively. Similarly, if OSC/CVM needs consultative help from other CVM scientists, for example, molecular biology, such consultative service will be pursued from the appropriate CVM office. The RPB Chief in consultation with the CFSAN Strategic Manager for Biotechnology and/or the Special Assistant to the Director of OSC/CVM, will recommend and request needed additional team members. In addition, senior managers such as the Strategic Manager for Biotechnology of CFSAN, the Special Assistant to the Director of OSC/CVM and the RPB Chief will join the team when novel or precedent-setting issues are involved.

B. Procedures for Initial Consultation

1. Requests for consultations on bioengineered foods are coordinated by RPB/DPP/OPA/CFSAN and NLT/DAF/OSC/CVM. If the initial request comes to RPB, the RPB Chief designates a CSO to serve as the chairperson of the BET to coordinate the consultation. In the interest of centralizing the process, if the initial request was sent to CVM, the request (together with the name of the suggested representative from CVM to serve as chairperson for the BET team) will be forwarded to RPB/DPP/OPA/CFSAN where files are established and records are maintained.
2. The BET chairperson completes a "contact form" (attachment 1) and forwards it together with the consultation request to the Document Control Center (DCC) to open a biotechnology notification file (BNF). If the contact initiating a consultation is made by telephone, a memorandum of the telephone contact will be prepared and forwarded to DCC with the "contact form" (attachment 1). In addition to the blue copy of the memorandum that is sent to DCC, copies of this, as well as other memoranda and correspondence, should be sent to HFS-13 (CFSAN's Strategic Manger for Biotechnology), HFS-206 (RPB/DPP/OPA/CFSAN), HFV-228 (NLT/DAF/OSC/CVM) and HFV-200 (the Special Assistant to the Director of OSC/CVM).
3. DCC establishes a BNF, assigns the consultation a BNF number, and enters it into the Scientific Information Retrieval and Exchange Network (SIREN).
4. The chairperson responds to the developer (by phone or letter) indicating: 1) receipt of the letter/submission requesting consultation, 2) the BNF number assigned to the consultation and to be used in all future communications, and 3) the date and place of the consultation meeting when necessary. The chairperson will be the primary contact person for all future communications between the developer and FDA.
5. The chairperson, in consultation with the Strategic Manager for Biotechnology, the RPB Chief, and the Special Assistant to the Director of OSC/CVM, determines whether additional team members are needed and requests that they be made available.
6. The chairperson notifies the BET members of the new consultation; if any material is submitted by the developer as part of the consultation, the chairperson distributes copies of the material to the BET members. In consultation with the BET members, the chairperson may convene a premeeting to discuss regulatory and scientific issues prior to meeting with the developer.

7. The chairperson conducts the consultation meeting at which scientific, regulatory, and policy issues are discussed with the developer. While the team will work as a unit to evaluate issues, advice regarding specific questions, especially those aimed at issues the developer might need to address, is primarily the responsibility of the BET member with the appropriate expertise. The chairperson prepares a memorandum of meeting with concurrence from the BET members as appropriate.
8. The chairperson is responsible for making sure that the entry for the BNF is accurate and up to date by making entries for each action (e.g., memo of phone conversation, any additional incoming material, memo of meeting, any outgoing correspondence, etc., see attachment 2).

C. Procedures for Final Consultations

1. When the firm has accumulated the information that it believes is adequate to ensure that the product complies with the relevant provisions of the Act, the firm is in a position to conclude any ongoing consultation and inform FDA about its intention to initiate commercial distribution by submitting a summary of the firm's safety and nutritional assessment to the agency. Upon receipt, the chairperson sends a letter to the developer acknowledging receipt of the notification. In the event that this is the first contact with FDA, the chairperson fills out a "contact form" (attachment 1), forwards it to DCC who will assign a BNF number and enter the notification in SIREN, and sends a letter acknowledging receipt of submission to the developer.
2. Within 10 days of receipt of the submission, the chairperson distributes copies of the submission to members of the BET for evaluation as to whether the summary contains sufficient information to demonstrate that the developer has addressed all matters relevant to the safety and regulatory status of the bioengineered food.
3. Within four weeks of receipt of the submission, the chairperson s eeks input (through a BET meeting or individual consultations) from BET members as to whether there are any safety or regulatory issues the firm has not addressed in the summary. The chairperson, or a BET member with the knowledge of the chairperson, communicates to the developer any needed additional information the BET feels that it needs in order to determine whether the developer has addressed all matters relevant to the safety and regulatory status of the bioengineered food.
4. The chairperson consults with the BET members to decide whether a meeting with the firm's scientists should be requested prior to closing the consultation. If a meeting is requested, the chairperson sets up a meeting of the BET with the firm's scientists (at headquarters, via video conference or telephone conference, depending on the circumstances) at which time the company's scientists would discuss the scientific basis for the firm's conclusions concerning the safety and regulatory status of their product. This meeting is intended to allow the BET to discuss the scientific data and information in more detail than would be provided in the firm's summary assessment document.
5. The chairperson writes a memorandum to the file describing the outcome of the consultation. The memorandum should be explicit as to whether 1) there are no further questions and whether the BET considers the consultation closed, 2) the bioengineered food is subject to the food additive petition provisions of the Act, or 3) there are other regulatory issues such as labeling requirements that need to be addressed. The memorandum will take into account any issues that have been raised and resolved regarding the firm's safety and nutritional assessment. The chairperson obtains concurrence from the relevant BET members and senior management, as necessary, before finalizing the memorandum.
6. Based on the recommendation of the BET, the chairperson drafts a letter to the firm (following the format of previously issued letters) for the signature of the Director of OPA/CFSAN, indicating the outcome of the consultation. After concurrence by the RPB Chief, the CFSAN Strategic Manager for Biotechnology, the Director of DPP, the Special Assistant to the Director of OSC/CVM, and the Director of OSC/CVM, the chairperson finalizes the letter for the signature of the Director of OPA/CFSAN and the letter is issued.
7. The chairperson provides information on the notification to HFS-551 for inclusion in the list of completed consultations on the World Wide Web.

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*Effective June 18, 2001, Office of Premarket Approval is now Office of Food Additive Safety.

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