DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC

JUN 6 2003

Mr. A. R. Middaugh
Executive Director
National Potato Council
5690 DTC Boulevard
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Englewood, Colorado 80111-3200

Dear Mr. Middaugh:

This is in response to your letter of March 10, 2000, thanking the Food and Drug Administration (FDA) for meeting with members of the National Potato Council's Board of Directors to discuss your concerns regarding biotechnology and the labeling of foods. We regret the delay in responding.

We appreciate the additional information you sent to us regarding Dr. Tomas Hogan's presentation about consumer acceptance of biotechnology. We also appreciate the booklet you sent on biotechnology that was printed in Canada.

As you may be aware, on January 18, 2001, FDA published a draft guidance document entitled "Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." We are enclosing a copy of the draft guidance. FDA published this draft guidance to assist manufacturers who wish to voluntarily label their foods being made with or without the use of bioengineered ingredients. We will forward a copy of your letter to our Dockets Management Branch to be filed under docket number 00D-1598.

Please be assured that we will consider all comments before making a final decision on the labeling of bioengineered foods. We look forward to working with you in the future.

Sincerely yours,

Catalina Ferré-Hockensmith

Catalina Ferré-Hockensmith
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Enclosure

00D-1598

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Guidance for Industry

Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering

Draft Guidance

This guidance document is being distributed for comment purposes only.

Draft released for comment January 2001.

Comments and suggestions regarding this draft document should be submitted by to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with Docket Number 00D-1598. For questions regarding this draft document contact Catalina Ferre-Hockensmith, (202) 205-4168.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Guidance for Industry

Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering

Draft Guidance

This draft guidance represents FDA's current thinking on voluntary labeling of foods indicating whether foods have or have not been developed using bioengineering. 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 an approach satisfies the requirements of applicable statutes and regulations. The draft guidance is being distributed for comment purposes in accordance with FDA's Good Guidance Practices (65 FR 56468, September 19, 2000).

BACKGROUND

In the Federal Register of May 29, 1992 (57 FR 22984), FDA published its "Statement of Policy: Foods Derived from New Plant Varieties" (the 1992 policy). The 1992 policy applies to foods developed from new plant varieties, including varieties that are developed using recombinant deoxyribonucleic acid (rDNA) technology (which is often referred to as "genetic engineering" or "biotechnology"). This guidance document refers to foods derived from plant varieties that are developed using rDNA technology as "bioengineered foods." In addition, because the Federal Food Drug, and Cosmetic Act (the act) defines food as articles used for food or drink for man or other animals, this

guidance document applies to animal feeds as well as to human foods. The 1992 policy provides guidance to industry on scientific and regulatory issues related to bioengineered foods and solicited written comments from interested persons. The policy includes guidance on questions to be answered by developers of foods from new plant varieties, to ensure that the new products are safe and comply with applicable legal requirements. It also encourages continuation of the general practice of the food industry to consult with the agency about the safety of new foods, e. g., bioengineered foods.

In the 1992 policy, FDA also addresses the labeling of foods derived from new plant varieties, including plants developed by bioengineering. The 1992 policy does not establish special labeling requirements for bioengineered foods as a class of foods. The policy states that FDA has no basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.

To fully understand the agency's mandate and authority in requiring labeling of foods, one must refer to the Federal Food, Drug, and Cosmetic Act (the act) to determine the extent to which the agency is charged with governing labeling of foods. Section 403 governs the labeling of foods. Under section 403(a)(1), a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act provides additional guidance on how labeling may be misleading. It states that labeling is

misleading if it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. While the legislative history of section 201(n) contains little discussion of the word "material," there is precedent to guide the agency in its decision regarding whether information on a food is in fact material. Historically, the agency has generally interpreted the scope of the materiality concept to mean information about the attributes of the food itself. FDA has required special labeling on the basis of it being "material" information in cases where the absence of such information may: 1) pose special health or environmental risks (e.g., warning statement on protein products used in very low calorie diets); 2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are made about a product); or 3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine not suitable for frying).

Although the 1992 policy does not require special labeling for bioengineered foods, the agency advised in that policy that labeling requirements that apply to foods in general also apply to foods produced using biotechnology. Section 403(i) of the act requires that each food bear a common or usual name or, in the absence of such a name, an appropriately

descriptive term. In addition, under section 201(n), the label of the food must reveal all material facts about the food. Thus:

- If a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.

- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the label to describe the issue.

- If a bioengineered food has a significantly different nutritional property, its label must reflect the difference.

- If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.

In the Federal Register of April 28, 1993 (58 FR 25837), the agency requested data and information on certain labeling issues that had arisen from the labeling guidance in the 1992 policy. In 1999, the agency announced that it would hold three public meetings (64 FR 57470; October 25, 1999). The purpose of those meetings was for the agency to share its current approach and experience over the

previous five years regarding bioengineered foods, to solicit views on whether FDA's policies should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply. The agency received more than 50,000 written comments about its policy regarding safety and labeling of bioengineered foods. The theme related to labeling in those comments and the testimony at the meetings was that there are very strongly held but divergent views as to whether bioengineered foods should be required to bear special labeling. However, there was general agreement that providing more information to consumers about bioengineered foods would be useful. A number of comments supported the need for guidance from FDA regarding appropriate ways that industry could voluntarily provide information on a food label about bioengineering.

FDA has reviewed information in the comments received in response to the 1992 policy and the 1993 information request as well as the comments from the 1999 meetings. Most of the comments that addressed labeling requested mandatory disclosure of the fact that the food or its ingredients was bioengineered or was produced from bioengineered food. However, these comments did not provide data or other information regarding consequences to consumers from eating the foods or any other basis for FDA to find under section 201(n) of the act that such a disclosure was a material fact. Many of the comments expressed concern about possible long term consequences from consuming bioengineered foods, but they

did not contend that any of the bioengineered foods already on the market have adverse health effects. The comments were mainly expressions of concern about the unknown. The agency is still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act. FDA is therefore reaffirming its decision to not require special labeling of all bioengineered foods.

The agency is providing the following guidance to assist manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients. While the use of bioengineering is not a material fact, many consumers are interested in the information, and some manufacturers may want to respond to this consumer desire. The guidance was developed using information from the comments and from focus groups, as well as other resources, and is intended to help ensure that labeling is truthful and not misleading.

GUIDANCE

In determining whether a food is misbranded, FDA would review label statements about the use of bioengineering to develop a food or its ingredients under sections 403(a) and 201(n) of the act. Under section 403(a) of the act, a food is

misbranded if statements on its label or in its labeling are false or misleading in any particular. Under section 201(n), both the presence and the absence of information are relevant to whether labeling is misleading. That is, labeling may be misleading if it fails to disclose facts that are material in light of representations made about a product or facts that are material with respect to the consequences that may result from use of the product. In determining whether a statement that a food is or is not genetically engineered is misleading under sections 201(n) and 403(a) of the act, the agency will take into account the entire label and labeling.

Statements about foods developed using bioengineering

FDA recognizes that some manufacturers may want to use informative statements on labels and in labeling of bioengineered foods or foods that contain ingredients produced from bioengineered foods. The following are examples of some statements that might be used. The discussion accompanying each example is intended to provide guidance as to how similar statements can be made without being misleading.

- "Genetically engineered" or "This product contains cornmeal that was produced using biotechnology."

The information that the food was bioengineered is optional and this kind of simple statement is not likely to be misleading. However, focus group data indicate that

consumers would prefer label statements that disclose and explain the goal of the technology (why it was used or what it does for/to the food) (Ref. 1). Consumers also expressed some preference for the term "biotechnology" over such terms as "genetic modification" and "genetic engineering" (Ref. 1).

- "This product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat."

This example includes both required and optional information. As discussed above in the background section, when a food differs from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference. Because this soybean oil contains more oleic acid than traditional soybean oil, the term "soybean oil" no longer adequately describes the nature of the food. Under section 403(i) of the act, a phrase like "high oleic acid" would be required to appear as part of the name of the food to describe its basic nature. The statement that the soybeans were developed using biotechnology is optional. So is the statement that the reason for the change in the soybeans was to reduce saturated fat.

- "These tomatoes were genetically engineered to improve texture."

In this example, the change in texture is a difference that may have to be described on the label. If the texture improvement makes a significant difference in the finished product, sections 201(n) and 403(a)(1) of the act would require

disclosure of the difference for the consumer. However, the statement must not be misleading. The phrase "to improve texture" could be misleading if the texture difference is not noticeable to the consumer. For example, if a manufacturer wanted to describe a difference in a food that the consumer would not notice when purchasing or consuming the product, the manufacturer should phrase the statements so that the consumer can understand the significance of the difference. If the change in the tomatoes was intended to facilitate processing but did not make a noticeable difference in the processed consumer product, a phrase like "to improve texture for processing" rather than "to improve texture" should be used to ensure that the consumer is not misled. The statement that the tomatoes were genetically engineered is optional.

- "Some of our growers plant tomato seeds that were developed through biotechnology to increase crop yield."

The entire statement in this example is optional information. The fact that there was increased yield does not affect the characteristics of the food and is therefore not necessary on the label to adequately describe the food for the consumer. A phrase like "to increase yield" should only be included where there is substantiation that there is in fact the stated difference.

Where a benefit from a bioengineered ingredient in a multi-ingredient food is described, the statement should be worded so that it addresses the ingredient and

not the food as a whole; for example, "This product contains high oleic acid soybean oil from soybeans produced through biotechnology to decrease the level of saturated fat." In addition, the amount of the bioengineered ingredient in the food may be relevant to whether the statement is misleading. This would apply especially where the bioengineered difference is a nutritional improvement. For example, it would likely be misleading to make a statement about a nutritionally improved ingredient on a food that contains only a small amount of the ingredient, such that the food's overall nutritional quality would not be significantly improved.

FDA reminds manufacturers that the optional terms that describe an ingredient of a multi-ingredient food as bioengineered should not be used in the ingredient list of the multi-ingredient food. Section 403(i)(2) of the act requires each ingredient to be declared in the ingredient statement by its common or usual name. Thus, any terms not part of the name of the ingredient are not permitted in the ingredient statement. In addition, 21 CFR 101.2(e) requires that the ingredient list and certain other mandatory information appear in one place without other intervening material. FDA has long interpreted any optional description of ingredients in the ingredient statement to be intervening material that violates this regulation.

Statements about foods that are not bioengineered or that do not contain ingredients produced from bioengineered foods

Terms that are frequently mentioned in discussions about labeling foods with respect to bioengineering include "GMO free" and "GM free." "GMO" is an acronym for "genetically modified organism" and "GM" means "genetically modified." Consumer focus group data indicate that consumers do not understand the acronyms "GMO" and " GM" and prefer label statements with spelled out words that mean bioengineering (Ref. 1).

Terms like "not genetically modified" and "GMO free," that include the word "modified" are not technically accurate unless they are clearly in a context that refers to bioengineering technology. "Genetic modification" means the alteration of the genotype of a plant using any technique, new or traditional. "Modification" has a broad context that means the alteration in the composition of food that results from adding, deleting, or changing hereditary traits, irrespective of the method. Modifications may be minor, such as a single mutation that affects one gene, or major alterations of genetic material that affect many genes. Most, if not all, cultivated food crops have been genetically modified. Data indicate that consumers do not have a good understanding that essentially all food crops have been genetically modified and that bioengineering technology is only one of a number of technologies used to genetically modify crops. Thus, while it is accurate to say that a bioengineered food was "genetically modified," it likely would be inaccurate to state that a food that had not been produced using biotechnology

was "not genetically modified" without clearly providing a context so that the consumer can understand that the statement applies to bioengineering.

The term "GMO free" may be misleading on most foods, because most foods do not contain organisms (seeds and foods like yogurt that contain microorganisms are exceptions). It would likely be misleading to suggest that a food that ordinarily would not contain entire "organisms" is "organism free."

There is potential for the term "free" in a claim for absence of bioengineering to be inaccurate. Consumers assume that "free" of bioengineered material means that "zero" bioengineered material is present. Because of the potential for adventitious presence of bioengineered material, it may be necessary to conclude that the accuracy of the term "free" can only be ensured when there is a definition or threshold above which the term could not be used. FDA does not have information with which to establish a threshold level of bioengineered constituents or ingredients in foods for the statement "free of bioengineered material." FDA recognizes that there are analytical methods capable of detecting low levels of some bioengineered materials in some foods, but a threshold would require methods to test for a wide range of genetic changes at very low levels in a wide variety of foods. Such test methods are not available at this time. The agency suggests that the term "free" either not be used in bioengineering label statements or that it be in a context that makes clear that a zero level of bioengineered

material is not implied. However, statements that the food or its ingredients, as appropriate, was not developed using bioengineering would avoid or minimize such implications. For example,

- "We do not use ingredients that were produced using biotechnology;"
- "This oil is made from soybeans that were not genetically engineered;" or
- "Our tomato growers do not plant seeds developed using biotechnology."

A statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies that the labeled food is superior to foods that are not so labeled. FDA has concluded that the use or absence of use of bioengineering in the production of a food or ingredient does not, in and of itself, mean that there is a material difference in the food. Therefore, a label statement that expresses or implies that a food is superior (e.g., safer or of higher quality) because it is not bioengineered would be misleading. The agency will evaluate the entire label and labeling in determining whether a label statement is in a context that implies that the food is superior.

In addition, a statement that an ingredient was not bioengineered could be misleading if there is another ingredient in the food that was bioengineered. The claim must not misrepresent the absence of bioengineered material. For example, on a product made largely of bioengineered corn flour and a small amount of

soybean oil, a claim that the product "does not include genetically engineered soybean oil" could be misleading. Even if the statement is true, it is likely to be misleading if consumers believe that the entire product or a larger portion of it than is actually the case is free of bioengineered material. It may be necessary to carefully qualify the statement in order to ensure that consumers understand its significance.

Further, a statement may be misleading if it suggests that a food or ingredient itself is not bioengineered, when there are no marketed bioengineered varieties of that category of foods or ingredients. For example, it would be misleading to state "not produced through biotechnology" on the label of green beans, when there are no marketed bioengineered green beans. To not be misleading, the claim should be in a context that applies to the food type instead of the individual manufacturer's product. For example, the statement "green beans are not produced using biotechnology" would not imply that this manufacturer's product is different from other green beans.

Substantiation of label statements

A manufacturer who claims that a food or its ingredients, including foods such as raw agricultural commodities, is not bioengineered should be able to substantiate that the claim is truthful and not misleading. Validated testing, if available, is the

most reliable way to identify bioengineered foods or food ingredients. For many foods, however, particularly for highly processed foods such as oils, it may be difficult to differentiate by validated analytical methods between bioengineered foods and food ingredients and those obtained using traditional breeding methods. Where tests have been validated and shown to be reliable they may be used. However, if validated test methods are not available or reliable because of the way foods are produced or processed, it may be important to document the source of such foods differently. Also, special handling may be appropriate to maintain segregation of bioengineered and nonbioengineered foods. In addition, manufacturers should consider appropriate recordkeeping to document the segregation procedures to ensure that the food's labeling is not false or misleading. In some situations, certifications or affidavits from farmers, processors, and others in the food production and distribution chain may be adequate to document that foods are obtained from the use of traditional methods. A statement that a food is "free" of bioengineered material may be difficult to substantiate without testing. Because appropriately validated testing methods are not currently available for many foods, it is likely that it would be easier to document handling practices and procedures to substantiate a claim about how the food was processed than to substantiate a "free" claim.

FDA has been asked about the ability of organic foods to bear label statements to the effect that the food (or its ingredients) was not produced using biotechnology.

On December 21, 2000, the Agriculture Marketing Service of the U.S. Department of Agriculture (USDA) published final regulations on procedures for organic food production (National Organic Program final rule; 65 FR 80548). That final rule requires that all but the smallest organic operations be certified by a USDA accredited agent and lays out the requirements for organic food production. Among those requirements is that products or ingredients identified as organic must not be produced using biotechnology methods. The national organic standards would provide for adequate segregation of the food throughout distribution to assure that non-organic foods do not become mixed with organic foods. The agency believes that the practices and record keeping that substantiate the "certified organic" statement would be sufficient to substantiate a claim that a food was not produced using bioengineering.

References

1. Levy, A.S., Derby, B.M., "Report on Consumer Focus Groups on Biotechnology", Consumer Studies Team, Center for Food Safety and Nutrition, Food and Drug Administration, Washington, D.C., 2000

Rec: 3/10/00

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March 10, 2000

Dr. Christine Lewis, Acting Director
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Dear Dr. Lewis:

I want to accomplish several things with this letter. Initially we want to thank you for meeting with members of the National Potato Council's Board of Directors in Washington D.C. on March 1, 2000. We were very pleased with your understanding of the potato industry's concerns with regard to biotechnology in general and the labeling of foods in particular. We appreciate your understanding of the industry's position and your willingness to have us provide you with additional information.

In response to your request for any research regarding consumer acceptance of biotechnology, you will find enclosed with this letter a rather extensive presentation by Dr. Tomas Hoban, Professor at North Carolina State University. We have also enclosed a booklet printed in Canada which we feel clearly gives a broad background in food biotechnology.

We have not provided information to the Food and Drug Administration as requested in the Federal Register since we were well past the deadline date.

Hopefully, Dr. Lewis, this information will be of some value and please do not hesitate to advice us if we can provide further information.

Sincerely,

A. R. Middaugh
Executive Director

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NPC Position - Biotechnology

The NPC encourages the use of sound science in the EPA, USDA and FDA decision making process as well as by our international trading partners.

The NPC supports continued research into biotechnology for new potato varieties and products.

The NPC supports a thorough review by the private sector and mandatory consultation with all relevant regulatory agencies. Before the food or ingredient is introduced into interstate commerce the biotech company should file with FDA summary documentation to support the determination of safety for the biotech food and derivative ingredients before they are marketed. The NPC supports labeling if it is determined to be necessary to protect public health. Otherwise, the NPC opposes the mandatory labeling of safe biotech products once they are in the marketplace. Any claims on voluntary labels should be able to be substantiated.