CSPI Center for Science in the Public Interest
Publisher of *Nutrition Action Healthletter*

5538 '01 MAR 20 A10 :00

March 19, 2001

By Fax and Regular Mail
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments on Docket Number 00D-1598, Guidance for Industry on "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering."

The Center for Science in the Public Interest ("CSPI") submits the attached comments on the Food and Drug Administration's ("FDA") Draft Guidance for Industry on "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" ("Draft Guidance"). CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply and on reducing the damage caused by alcoholic beverages. CSPI seeks to promote health through educating the public about nutrition and alcohol; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by the more than 800,000 member-subscribers to its Nutrition Action Healthletter, through foundation grants, and through sales of educational materials. CSPI receives no funding from industry or the federal government.

To summarize our detailed comments, the Draft Guidance is a significant first step by FDA in addressing the controversial issue of labeling foods that have been derived in whole or part from ingredients that were genetically engineered. The Draft Guidance, however, needs significant improvements in order to provide meaningful guidance to both the industry that will carry out the labeling and the consumers who will be provided information by the label. Our comments point out many current gaps and ambiguities in the "Draft Guidance," including the need for specific definitions, thresholds, and additional examples of proper and improper labeling claims. If these comments are included in its final guidance, FDA will have taken a significant step in providing useful value-free, and non-disparaging information to consumers who seek to avoid or to purchase bioengineered products.

Although finalizing the Draft Guidance will provide consumers with some information about food products derived or not derived from genetically engineered crops, CSPI urges FDA to consider issuing regulations for mandatory labeling of such foods. Public opinion polls show that most consumers want to see labeling when foods are derived from genetically engineered crops. Page 5 of the Draft Guidance states that most commentors to FDA requested mandatory disclosure and that there is general agreement about the usefulness of providing more information to consumers about bioengineered foods. Mandatory labeling would help consumers

00D-1598 C 2985

Tel: (202) 332-9110
Fax: (202) 265-4954
Home Page: www.cspinet.org
E-mail: cspi@cspinet.org

Suite 300
1875 Connecticut Ave., N.W.
Washington, D.C. 20009-5728

Michael F. Jacobson, Ph.D.
Executive Director

who want to avoid -- or choose -- biotech foods because of concerns about health or the environment, or who don't have access to organic foods, which are not genetically engineered. Mandatory labeling would allow consumers to exercise choice in an informed manner, a process that may or may not occur under the voluntary Draft Guidance. FDA could require such labeling based on its authority to require facts that are "material in the light of . . . representations" made. 21 U.S.C. § 321(n).

Before issuing any mandatory labeling requirements, however, FDA should carefully consider the impact of labeling. FDA must ensure that the label disclosures will not mislead the public. Where genetically engineered foods have no nutritional, safety, or other human health difference from conventional foods, labeling should not deceive consumers into thinking that foods free of genetically engineered ingredients are quantitively or qualitatively different from foods with genetically engineered ingredients. The use of deceptive labeling claims about safety or superiority, whether specifically stated or merely implicit in a label, could lead to price gouging in the marketplace and/or substantial and unwarranted negative impacts on agricultural biotechnology and farmers. Careful analysis is needed by FDA about the effects of variously worded notices describing genetically engineered foods and the placement of that information on a product label before implementing a mandatory labeling system that would provide honest, objective, value-free and non-disparaging information.

CSPI appreciates this opportunity to submit comments on the Draft Guidance. CSPI understands that FDA has worked hard to address the controversial issue of labeling genetically engineered foods and hopes that FDA will continue to analyze both voluntary and mandatory labeling approaches more thoroughly in the coming months. If FDA would like additional information from CSPI about this letter and the attached detailed comments, I would be happy to meet with you at your convenience.

Sincerely,

Gregory Jaffe
Co-Director, Biotechnology Project
Center for Science in the Public Interest
202-332-9110, Ext. 369

Attachment

Specific Comments on FDA's Draft Guidance on *"Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering."*

1. FDA's Current Position on Approving Foods Derived from Genetic Engineering

The Background Section on pages 1-3 of the Draft Guidance should reflect FDA's current view about the special regulatory status of genetically engineered foods. Although the Background Section is correct from a historical perspective, it does not adequately state FDA's current position that bioengineered foods should require a mandatory safety review. In the currently proposed pre-market notification regulations, FDA recognizes that there is a difference between conventionally bred and genetically engineered plants and that the difference warrants a mandatory safety review by FDA of genetically engineered plants. That position should be reflected in the Draft Guidance to advise the public that before a label is attached to a product with a genetically engineered ingredient, the FDA has reviewed information that shows that the ingredient is safe for human consumption.

2. The Term "Bioengineering"

In the title and throughout the text of the Draft Guidance, the term "bioengineering" is used for plant varieties that were developed using rDNA technology. This term is not found anywhere in the 1992 FDA Statement of Policy and is not generally recognized throughout the literature on genetically engineered crops. Terms such as "genetic engineering" or "biotechnology" are much more familiar to consumers than "bioengineering." For labeling to be informative to consumers, it must contain terms that have broad recognition and an easily understood meaning. Therefore, CSPI suggests that FDA replace the term "bioengineering" with "genetic engineering" or "biotechnology." In addition, FDA should consider conducting surveys and/or additional focus groups with consumers to identify the best term to use. Moreover, whatever term is used in the final guidance should include a specific definition for that term so that all interested parties understand the scope of the guidance. The Draft Guidance does not include such a definition for "bioengineering."

3. Mandatory Labeling for Material Facts about Bioengineered Foods

In several places, the Draft Guidance identifies specific instances in which mandatory labeling of a bioengineered food would be required under Sections 403 and/or 201 of the Food Drug and Cosmetic Act ("Act"). These discussions are inadequate and provide virtually no guidance because they are extremely general and lack definitions. Page 4 of the Draft Guidance states that if a bioengineered food is "significantly different" from its traditional counterpart, it

must have a different name. Similarly, the Draft Guidance states on page 4 that if the bioengineered food has a "significantly different" nutritional property, the label must reflect the difference. In both of these instances, the Draft Guidance does not define "significantly different" in any manner. Is a statistically significant 1% difference in starch content enough to be considered significantly different for labeling purposes? In order for manufacturers to understand what is required on their labels, an explanation of these terms is needed in the guidance.

4. Statements About Foods Developed Using Bioengineering

CSPI suggests several changes to this section to make it as informative as possible to both manufacturers and consumers. First, it would be extremely helpful to have additional examples of labels that manufacturers can use for products containing genetically engineered crops, particularly labels that explain the benefits of those crops. For example, some genetically engineered crops reduce the use of pesticides. How might a manufacturer capture such benefits in a label statement that is not misleading? Guidance on this would be extremely helpful, especially if any manufacturer is going to voluntarily label that their product includes bioengineered ingredients.

Second, additional guidance is needed on labeling of a multi-ingredient food. Virtually all products today that would be labeled under this Draft Guidance are multi-ingredient foods and yet only one paragraph of the Draft Guidance addresses this situation. Additional examples of how to label these products so that they are not misleading are necessary. This is especially important since current food label regulations do not require manufacturers to identify the amount or percentage of an ingredient in a particular product.

Third, where a label will state a reason for the biotechnology crop, such as the Draft Guidance's example on page 9 regarding tomato seeds with increased yield, the Draft Guidance does not quantify how big the "increase" must be to substantiate the claim and avoid a misleading statement. Where a manufacturer wants to make a claim of increased yields, decreases in pesticides, or some other tangible benefit, the Draft Guidance needs to discuss when those claims will be deemed misleading.[1] Without more specifics, manufacturers may choose

[1] For the specific example in the Draft Guidance, two additional pieces of information are necessary. First, manufacturers need to know if they can substantiate this process claim by showing that the tomato seeds were developed to increase yield, even if in practice there is no appreciable yield increase. Second, if an increase in yield must be shown, what is the threshold

not to label biotech foods for fear that their claim will be deemed misleading even when knowledge about the tangible benefits from the genetically engineered product would be important to consumers.

Fourth, the Draft Guidance should address how much of a single ingredient food must be genetically engineered in order for it to be labeled as derived from genetic engineering. For example, what percentage of the tomatoes used to make tomato paste must be genetically engineered to substantiate a label claim that the product was derived from genetically engineered tomatoes? Would it need to be produced with 100% genetically engineered tomatoes or would 50% or some other number be sufficient.

Finally, CSPI asks FDA to reconsider its position on page 10 that only the name of an ingredient is permitted in the ingredient statement as it relates to the labeling of genetically engineered ingredients. FDA regulations currently require that if a food contains a chemical preservative, the label declaration shall state both the common name and a separate description of its function. 21 CFR Section 101.22. If a similar exception were allowed for genetically engineered ingredients, a manufacturer could put "genetically engineered corn" or "genetically modified corn (which decreases pesticides use)" instead of "corn" in the ingredient list, providing useful information for the consumer without prominently addressing this ingredient somewhere else on the product package. This might help eliminate the problem that many manufacturers fear from statements about bioengineered foods -- that no matter how neutral a statement, any statement set out from the ingredient list will be interpreted by many consumers as a statement of concern about the safety or purity of the product.

5. Avoidance Claims That Are Not Misleading and the Need for Thresholds

One of the most important labeling issues for consumers is that a label not mislead. For this reason, CSPI believes that the section of the Draft Guidance entitled "Statements About Foods That Are Not Bioengineered" needs to be expanded upon to clearly articulate when claims will be considered misleading. Claims of avoidance of genetically engineered ingredients could easily be interpreted by the public as implying superiority or added safety unless the wording,

---

increase that would substantiate using the term "increased"? Would a 1% increase be sufficient or should it be 10%, 20% or some other number? The standard of comparison should also be defined, such as the specific variety that the genetically engineered variety was derived from or the crop as a whole. If the latter, the substantial variation between varieties, especially under different growing conditions, should be addressed.

placement, and emphasis (*e.g.* size of the text) of the label statement were done properly or if an appropriate explanatory statement were included. The Draft Guidance discusses three examples of language on page 13 that FDA states would not be misleading but more examples would be extremely helpful. However, it is not just the text of the label but also where the text is placed and how it is emphasized which might lead to an interpretation that the product is superior, inferior, or more or less safe than another similar product. FDA should provide guidance about where language addressing genetically engineered ingredients should be placed (*e.g.* front, back, top, bottom; under ingredient box, etc...) and how it may be displayed (*e.g.* size of print, font, etc...). In addition, the criteria that FDA will use to decide if the label is misleading should be identified in the guidance. The Draft Guidance only states that the FDA will look at the entire label, without providing guidance on what criteria the FDA will consider in deciding whether an avoidance claim is misleading.

This section of the Draft Guidance also discourages the use of the term "free" in avoidance claims because there is no definition or threshold above which the term could not be used. Although misleading if left undefined, the term "free" is easily understood by consumers and imparts extremely useful information. CSPI strongly urges that FDA establish definitions and thresholds so that the term "free" can be used. FDA could establish both a threshold percentage under which a manufacturer could use the term "free" based on current science and crop contamination analysis and still allow an avoidance label based on the method of production (i.e. "Made from soybeans that were not genetically engineered"). The FDA currently permits terms like sodium-free to be used, even though the labeled foods may contain small amounts of and sodium. See 21 CFR § 101.61 and 21 CFR § 101.13(e). FDA should also consider defining the term "major ingredients" so that a manufacturer whose major ingredients were not developed with genetic engineering could label their product with a phrase such as "this product does not contain any major ingredients that were genetically engineered."

6. Use of Terms GMO and GM

CSPI agrees that the term organism should be considered misleading and not allowed on a label if that food does not normally contain entire live engineered organisms. Also, CSPI agrees that "genetically modified" does encompass both traditional breeding and genetic engineering and therefore is misleading unless the context is specified. However, the Draft Guidance needs to specify with examples what language would provide a clear context so that the consumer would understand that "genetically modified" applies only to "bioengineering." Finally, CSPI agrees that identifying one ingredient of a multi-ingredient product as not bioengineered when the rest of the product has one or more bioengineered ingredients is misleading and should not be allowed.

CSPI Comments on Voluntary Labeling Guidance

7. Substantiation of Label Statements

CSPI strongly agrees with the Draft Guidance statement that the manufacturer of the finished consumer product bears the burden of substantiating the claim. CSPI also agrees that testing is not necessary to substantiate labeling a food as either containing or not containing genetically engineered ingredients. Requiring testing in all cases would significantly increase the cost of labeling, reduce the number of manufacturers voluntarily deciding to label, and significantly decrease the information that might be provided to the consumer from the Draft Guidance. In addition, testing costs would be passed onto the consumer.

CSPI does suggest to FDA, however, that it set forth in more detail the documentation that would be sufficient to substantiate a label regarding genetic engineering. For example, the Draft Guidance states that "in some situations" certifications or affidavits "may be adequate to document that foods are obtained from the use of traditional methods." For which situations would it be adequate? When would it be inadequate? If it was inadequate, what else other than testing would be sufficient? Those questions need to be answered to provide guidance that would adequately inform manufacturers about their obligations and protect consumers from deception. Similarly, the Draft Guidance discusses "special handling" and "segregation" as potentially appropriate to substantiate a label. What types of special handling is FDA suggesting? When would it be needed? Does a manufacturer need to segregate to insure 100% bioengineered corn if they make a claim of "made with genetically engineered corn"? Answering such questions and setting forth more guidance on substantiating a label statement is important. Different amounts of information needed to substantiate a label would affect the cost of labeling, the cost of products with labels to consumers, and the likelihood that a manufacturer would undertake to voluntarily label.

8. Organic Foods as Foods Not Produced Using Bioengineering

CSPI agrees with the Draft Guidance's position that the practices and record keeping that substantiate a "certified organic" label are sufficient to substantiate a claim that a food was not produced using genetic engineering.

9. Enforcement of the Draft Guidance

The Draft Guidance sets forth a system for labels but does not discuss enforcement anywhere. If one goes into the supermarket today, one would find numerous products that do not conform with the current Draft Guidance. For example, some products currently state "NON

GMO Soy" or "Grown without GMO" on their labels. CSPI recommends that FDA include in the Draft Guidance a section on enforcement.[2] That section should discuss what actions FDA will take to insure that existing labels conform with the final Guidance. It should also discuss what activities FDA will carry out prospectively to verify that labels are in fact truthful and that the manufacturer of the product has adequately substantiated any information on the label. Without enforcement of the Draft Guidance, manufacturers may not comply, and consumers may not receive the information they rightly deserve. CSPI notes that FDA has asserted many times in recent decades that it did not have the resources to detect and stop economic deceptions and we question the reliability of new label rules that the FDA is not able to enforce.

10. Information Actually Provided by the Voluntary System to Public

Even if the Draft Guidance were modified as suggested above, little additional information would actually be provided to consumers of food products produced with or without genetically engineered ingredients. The FDA analysis of the Draft Guidance for purposes of the Paperwork Reduction Act ("PRA") is illustrative of how little new information would actually be provided. In the analysis, FDA does not anticipate that any manufacturers who use genetically engineered ingredients would actually label their products to that effect. That is not surprising given the current controversy over genetically engineered products and the lack of a mandatory system that would put all manufacturers on equal footing. One can easily conceive of a situation in which a manufacturer that labeled its product as containing genetically engineered ingredients would immediately be boycotted by certain groups, decreasing its current market share compared to other companies that remained silent about their use of a similar ingredient. Thus, even with a voluntary guidance, the vast majority of products on the market will remain silent about ingredients that came from genetically engineered crops. The PRA analysis suggests that all labeling in this area will be avoidance claims, of which the vast majority will come from organic products. That will actually provide no new information to the public as the labeling of an organic product already encompasses the fact that the product does not contain any genetically engineered ingredients.

For that reason, CSPI urges FDA to consider a mandatory labeling requirement that would provide consumers with the information they value in making informed purchasing decisions. FDA could require that labeling of all genetically engineered foods based on its authority to require disclosure of facts that are "material in the light of . . . representations" made.

---

[2] CSPI understands that as a voluntary Guidance, there is no penalty for noncompliance (i.e., for a manufacturer to decide to label or not to label). However, if a manufacturer does decide to label, then the do's and don'ts in this Guidance could be enforced under Sections 403 and 201 of the Act.

21 U.S.C. § 321(n). A material fact is one that may influence consumer purchasing decisions. See 58 Fed. Reg. 2850, 2863 (1993). Surveys, taken at face value, indicate that most Americans favor labeling of genetically engineered foods, and it is reasonable to conclude that label disclosure would affect the purchasing decisions of many consumers. Hence, the failure to disclose the presence of a genetically engineered ingredient in light of the representation that the package contains a traditional food product could be construed to constitute an omission of a material fact.

A mandatory labeling system that was properly structured to provide useful, value-free, and non-disparaging information, that did not add significant costs to consumers, and that allowed society to benefit from agricultural biotechnology is something that FDA needs to investigate carefully. CSPI believes that an appropriately structured mandatory labeling system would receive widespread support in our society from consumers, environmentalists, and industry.