DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1598]

Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA (we)) is announcing the availability of a draft guidance for industry entitled ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.'' FDA developed this draft guidance to assist manufacturers, who wish to voluntarily label their foods (human and animal) as being made with or without bioengineering or the use of bioengineered ingredients, to ensure that labeling is truthful and not misleading. FDA is taking this action in response to requests from food manufacturers and as part of the Clinton administration's initiatives to strengthen science-based regulation of bioengineered foods and consumer access to information.

DATES: Submit written comments concerning the draft guidance to ensure adequate consideration in the preparation of a revised guidance, if warranted, by March 19, 2001. However, you may submit written comments at any time. Submit written comments concerning the collection of information by March 19, 2001.

ADDRESSES: Submit written comments on the draft guidance and the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify the comments with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the draft guidance entitled ''Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering'' to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your request, or include a fax number to which the draft guidance may be sent. Alternatively, you may request a copy of the draft guidance by calling 202–205–4561, or you may fax your request to 202–205–4594. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Regarding human food issues: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

Regarding animal feed issues: William D. Price, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6652.

SUPPLEMENTARY INFORMATION:

I. 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 (human and animal) developed from new plant varieties, including varieties that are developed using recombinant deoxyribonucleic acid (rDNA) technology, which is often referred to as ''genetic engineering,'' ''biotechnology,'' or ''bioengineering.'' The 1992 policy provides guidance to industry on scientific and regulatory issues related to bioengineered foods and solicited written comments from interested persons. It 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.

In the 1992 policy, we also address 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 1992 policy states that we have no basis for concluding that bioengeered 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.

Although we do not require special labeling for bioengineered foods, as a class of foods, in the 1992 policy we advised that labeling requirements that apply to foods in general also apply to foods produced using biotechnology. Section 403(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(i)) 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) of the act (21 U.S.C. 321(n)), the labeling of food must reveal all facts that are material in light of representations made in the labeling or in light of consequences that may result from the use of the foods. 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 labeling to describe the issue.
- If a bioengineered food has a significantly different nutritional property, its labeling 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 in the labeling.

In the **Federal Register** of April 28, 1993 (58 FR 25837), we requested data and information (the 1993 information request) on certain labeling issues that had arisen from the labeling guidance in the 1992 policy. In 1999, we held three public meetings (64 FR 57470, October 25, 1999). The purpose of those meetings was for us to share our current approach and experience over the previous 5 years regarding bioengineered foods, to solicit views on whether our 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. We received more than 50,000 written comments about our 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.

We have reviewed information in the comments received in response to the 1992 policy and the 1993 information request as well as the comments from the meetings held in 1999. 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 us 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. We are 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. We are, therefore, reaffirming our decision to not require special labeling of all bioengineered foods.

We are providing guidance to assist manufacturers who wish to label their foods voluntarily 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. We developed this guidance using information from the comments and from focus groups, as well as other resources. The guidance is intended to help manufacturers ensure that their labeling is truthful and not misleading. In addition, because the act defines food as articles used for food or drink for man or other animals, this guidance applies to animal feeds as well as to human foods.

The guidance addresses the use of statements in the labeling of foods that are bioengineered or contain bioengineered ingredients. It is intended to provide guidance on how a manufacturer may make statements in the labeling about bioengineered foods and ingredients, without such statements being false or misleading.

The guidance also addresses the use of statements in the labeling that indicate that the food, or its ingredients, was not bioengineered. The agency is soliciting comments on the entire guidance document, but it is particularly interested in comments on how the draft guidance deals with statements like ''GMO free,'' ''GM free,'' ''biotech free,'' and ''no genetically engineered materials.'' For example, we are seeking comment on whether, and how, statements like ''GM free'' or ''no genetically engineered material'' can be made without being false or misleading. In the guidance document, FDA advises that the term ''free'' may be difficult to use without being false or misleading. If it implies ''zero,'' it may be very difficult to substantiate. The adventitious presence of bioengineered material may make a ''zero'' claim inaccurate. Further, these terms would be misleading if they imply that the food is superior because the food is not bioengineered. We have concluded that the use, or absence of use, of bioengineering in the production of a food is not a fact that is material either with respect to consequences resulting from the use of the food or due to representations on the labeling.

We suggest in the guidance that terms like ''GM free'' and ''biotech free'' either not be used in bioengineering labeling statements or be in a context that makes clear that a zero level of bioengineered material is not implied. We recognize that the terms are popular among those manufacturers who have already made label statements that a food was not bioengineered. FDA requests comments on whether statements like ''GM free,'' ''biotech free,'' and ''no genetically engineered materials'' can be made without being false or misleading, and, if so, how. Does such a statement imply zero content of bioengineered material? If so, would a clarifying statement help the consumer to understand that there may be some low level of bioengineered material present? Should substantiation of no detectable bioengineered material be required in the absence of a clarifying statement? Does ''biotech free'' or another similar term imply that the labeled food is superior to foods that are not so labeled? If so, would a clarifying statement, for example, a statement that the absence of the use of bioengineering does not make the food superior to food not so labeled or to a bioengineered food or ingredient, clarify the term adequately? Would such a clarifying statement be needed in all instances or are there some uses of ''GM free'' and similar terms that would not imply that the labeled food is superior, and why? We specifically request comment on these as well as any other aspects of how to avoid false or misleading statements in the labeling about the absence of use of bioengineering in the production of a food or its ingredients.

This Level 1 draft guidance represents our current thinking on the voluntary labeling 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).

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Suggested Documentation for Substantiating Whether Foods Have or Have Not Been Developed Using Bioengineering

Description: The 1992 policy stated that the method of development of a new plant variety, including plants developed using bioengineering, is not information that is material under section 201(n) of the act and, therefore, would not be required in the labeling of

food. This conclusion is consistent with our historic interpretation of section 201(n) of the act, in that the method of plant breeding is not required to be disclosed in labeling. In the 1993 information request, we requested additional information on labeling issues that had risen from our 1992 policy. Subsequently, in 1999, we held three public meetings to get public input on our existing policy with regard to its premarket review of foods produced through biotechnology and the labeling of such products. In response to comments that we received on our 1992 policy, the 1993 information request, and the public meetings, we decided to develop guidance for voluntary labeling indicating whether foods have or have not been developed using bioengineering. This guidance will assist manufacturers in labeling foods that have or have not been developed using bioengineering so that the labeling statement is truthful, not misleading, and scientifically valid. The information that the manufacturers will collect is documentation of handling practices so that they can truthfully label their products to indicate, if they so choose, whether the food has or has not been developed using bioengineering.

In general, FDA anticipates that manufacturers that claim that a product is not developed using bioengineered material would substantiate the claim. If validated testing is not available to ensure the absence of bioengineered material for a specific food, we suggest that manufacturers document handling practices to substantiate a claim that a food was not developed using bioengineering, rather than using a ''free'' claim. Thus, to substantiate handling practices, the manufacturers would have to document the source of such foods. Examples of documentation that we anticipate will demonstrate handling practices and procedures about how the food was processed are recordkeeping, certifications or affidavits from farmers, processors, and others in the food production and distribution chain. We are neither suggesting that firms maintain a certain set list of documents nor are we suggesting that anything less or different would likely be considered unacceptable. Rather, we are leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was produced using traditional methods.

Description of Respondents: Manufacturers of foods that were and were not produced using bioengineering.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Operating and Maintenance Costs	Total Hours
893	21	18,753	1	$1,781,400	18,753

[1] There are no capital costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Operating and Maintenance Costs	Total Hours
68	26	1,768	1	$53,040	1,768

[1] There are no capital costs associated with this collection of information.

FDA estimates that almost all of the organic producers and manufacturers who have issued statements that they will not use bioengineered ingredients will choose to label, and therefore, will incur the reporting burden. We determined the estimates for the annual reporting burden by using the approximately 18,753 products (16,985 organic products and 1,768 non-organic products) from producers who may not use bioengineered ingredients in their products. These manufacturers include producers who market to a niche of consumers who choose not to use products with bioengeered ingredients and manufacturers who have stated that they do not use bioengineered ingredients in their products. We estimated that the numbers of firms that will choose to label is 893 (825 firms for organic products and 68 for non-organic products). We estimated that the manufacturers of these products would choose to state on their label and in their labeling that those products were not developed using bioengineering. Such labeling would increase their paperwork burden. The estimates on the annual reporting burden (table 1 of this document) are based on agency knowledge of, and experience with, food labeling. The 18,753 product estimate may be too low if FDA has been unable to identify all producers that could use non-bioengineering labels or if FDA's labeling guidance encourages producers who have not issued bioengineering statements to now use such statements on the label. On the other hand, this may be an overestimate if some producers, who have been making statements indicating that they will try to use foods that were not developed using bioengineering, choose not to label their products.

We believe that the burden associated with the voluntary labeling of foods that have not been developed using bioengineering would be a one-time burden for the small number of firms that would decide, voluntarily, to add this additional information to the labels for their products, separate from any other label changes for their products. We estimate that at least 90 percent of firms would coordinate the addition of the statement on the label that their products were not developed using bioengineering with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be included almost entirely in the cost of other voluntary or required labeling changes. The incremental cost for these 803 firms (893 x 90 percent) would be approximately $50 per label for 16,878 labels, or $843,900 total. For the remaining 90 firms that would not coordinate changes with other labeling changes, we estimate that the cost would be approximately $500 per label for 1,875 labels, or $937,500 total. The estimated total operating and

maintenance costs in table 1 of this document are, therefore, $1,781,400.

When determining the annual recordkeeping burden (table 2 of this document), we estimated that the number of firms that would maintain records to substantiate labeling that their products were not developed using bioengineering is the same as the number of respondents with the reporting burden minus the number of firms marketing organic products (i.e., 68). We did not include products that are labeled ''organic'' in the estimated annual recordkeeeping burden because according to a proposal in the **Federal Register** of March 13, 2000 (65 FR 13512), issued by the Agriculture Marketing Service of the U.S. Department of Agriculture, a food labeled as ''organic'' would not be permitted to contain bioengineered materials. Therefore, the 16,985 organic products available today would be able to bear a voluntary labeling statement that the food was not developed using bioengineering. Thus, there is no additional paperwork burden to substantiate a claim that a product is not developed using bioengineering for these products. Because most of the non-organic products whose producers have stated they will not use bioengineered ingredients are made by large firms for whom the verification process is not likely to impose a significant burden relative to the size of their operation, we assume that the paperwork processing time associated with testing or source verification for these products is approximately 1 hour for a total of 1,768 hours per year. Therefore, FDA estimated that the total recordkeeping burden would be 1,768 hours per year. Based on our experience, we have estimated that the overhead and maintenance cost are $30 per hour. The estimated total operating and maintenance cost in table 2 of this document are, therefore, $53,040 total.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by March 19, 2001, to ensure adequate consideration in the preparation of a revised guidance, if warranted. However, interested persons may submit written comments at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Submit to the Dockets Management Branch written comments concerning this collection of information by March 19, 2001. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of the draft guidance also is available on the Internet at http://www.cfsan.fda.gov/dms/.

Dated: November 15, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184): Extension

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to ensure that all qualified entities are accepted for membership in the OPTN.

The estimated annual response burden is as follows:

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
121.3(b)(2)—OPTN membership and application requirements for OPOs, hospitals, histocompatibility laboratories	30	1	30	40	1,200
121.6(c)—Submitting criteria for organ acceptance	900	1	900	0.1	90
121.6(c)—Sending criteria to OPOs	900	1	900	0.1	90
121.7(b)(4)—Reasons for Refusal	900	0.5	34,200	0.1	3,420
121.7(e)—Transplant to prevent organ wastage	900	0.5	420	0.1	42
121.9(b)—Designated Transplant Program Requirements	10	1	10	2	20