



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2000-D-0075]

Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants." The guidance is intended to help food manufacturers that wish to voluntarily label their plant-derived food products or ingredients (for humans or for animals) as having been made with or without bioengineering.

DATES: Submit either electronic or written comments on the guidance at any time. Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, the Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants." Also include the FDA docket number found in brackets in the heading of this document.

You may submit comments as follows:

### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2000-D-0075 for "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Regarding human food issues: Andrea Krause, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371. Regarding animal food issues: Kathleen Jones, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-7077. Regarding the information collection: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

#### I. Background

Section 403 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343) generally governs the labeling of foods. Under section 403(a)(1) of the FD&C Act, a food

is misbranded if its labeling is false or misleading in any particular.

Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, 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.

In the Federal Register of May 29, 1992 (57 FR 22984), we published a "Statement of Policy: Foods Derived from New Plant Varieties" (1992 Policy). The 1992 Policy applies to foods for humans and animals that are developed from new plant varieties, including varieties that are developed using recombinant deoxyribonucleic acid (rDNA) technology. This technology has long been referred to as "rDNA technology," "genetic engineering," or "bioengineering," and more recently, as "modern biotechnology."

In the 1992 Policy, we addressed, among other things, the labeling of foods derived from new plant varieties, including plants developed by bioengineering. In the 1992 Policy, we explained that we were not establishing special labeling requirements for foods from bioengineered plants as a class of foods because we did not find any basis for concluding that foods from bioengineered plants, as a class, differ from other foods in any meaningful or uniform way, or that foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.

In the Federal Register of January 18, 2001 (66 FR 4839), we announced the availability of a draft guidance for industry entitled "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." We received more than 155,000 comments on the draft guidance. Most comments were submitted by consumers. Other comments

represented the views of advocacy groups, trade organizations, organic grocers/food co-ops, private sector business, farming/farm bureaus, food manufacturers, crop developers, local governments, and academic researchers. We have considered the comments and revised the guidance as appropriate. We understand that consumers may want information about whether or not a food is developed through genetic engineering. Thus, we are providing guidance on voluntary labeling that will help manufacturers that would like to provide consumers with additional information about the foods they consume.

We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. In addition, this guidance does not preempt State food labeling requirements that are consistent with the Federal requirements described in the guidance and that are not otherwise expressly preempted by the FD&C Act.

## II. Paperwork Reduction Act of 1995

This final guidance contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). Under the PRA, Federal Agencies must obtain approval from 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 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, in the Federal Register of January 18, 2001, we gave interested persons 60 days to comment on the information collection provisions in the draft guidance (66 FR 4839 at 4840).

After publishing the 60-day notice requesting public comment, section 3507 of the PRA (44 U.S.C. 3507) requires Federal Agencies to submit the proposed collection to OMB for review and clearance. In compliance with 44 U.S.C. 3507, we have submitted the following proposed collection of information to OMB for review and clearance. FDA is issuing this final guidance subject to OMB approval of the collection of information. If the collection is approved, FDA will publish a notice in the Federal Register concerning OMB approval and providing an OMB control number.

Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants

OMB Control Number 0910-New

As noted, in the Federal Register of January 18, 2001, we announced the availability of the draft guidance document and requested public comment on the information collection provisions. Subsequently, we published a document in the Federal Register of October 31, 2003 (68 FR 62086), informing interested parties that the proposed collection of information had been submitted to the OMB for review and clearance under the PRA. However, we determined that the request for comments was issued prematurely. Thus, we withdrew the notice on November 21, 2003 (68 FR 65717). We are now reissuing the request for comments and submitting the proposed collection of information to OMB.

The guidance entitled "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants" is intended to assist manufacturers that wish

to voluntarily label their foods (human or animal) as being made with or without genetic engineering or the use of genetically engineered ingredients, to ensure that such labeling is truthful and not misleading. 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 genetic engineering.

In general, we anticipate that manufacturers claiming that a product is not developed using genetically engineered material would substantiate the claim. We suggest that manufacturers document practices and procedures to substantiate a claim that a food was not developed using genetic engineering. Examples of documentation that we anticipate will demonstrate practices and procedures are recordkeeping, and 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 judgment to maintain appropriate documentation to demonstrate that the food was produced using traditional methods.

Description of Respondents: The respondents to the proposed collection of information are manufacturers of foods that were or were not derived from genetically engineered plants who wish to voluntarily label their food products.

As noted, in the Federal Register of January 18, 2001, we published a 60-day notice requesting public comment on the proposed collection of information. We received more than 155,000 comments, each containing one or more issues. The following is a discussion of the comments we received on the information collection and our response to those comments.

(Comment 1) Most comments agreed that labeling food products as genetically engineered or non-genetically engineered would result in costs due to segregation, testing, or third-party validation, in addition to label changes. However, some comments said the producers that choose to label their products as non-genetically engineered and the consumers that choose to purchase these products should incur these costs. Other comments said that these costs should be borne by the growers, manufacturers, processors, and marketers of genetically engineered foods.

(Response) We disagree that it would be necessary to incur costs due to segregation, testing, or third-party validation to substantiate a claim that a food was not developed using genetic engineering. We also note that the question of who should bear the paperwork burden is not within the scope of the guidance.

(Comment 2) One comment stated that we underestimated the number of small firms that will choose to label their product as not genetically engineered, but will not attempt to make an organic claim.

(Response) We disagree that we underestimated the number of respondents in the 2001 60-day Federal Register notice. The comment did not offer any evidence to substantiate this claim or give an estimate of how many small firms will choose to make a non-genetically engineered claim. We based our estimate of the number of firms that would label their products with a genetically engineered claim on the number of products making an organic claim and the number of products that were not currently making an organic claim on their label, but were making a statement about genetic engineering on their Web site, through a press release, or other venue when the 2001 60-day notice was published. We have, however, updated in this notice the

estimated number of recordkeepers to reflect new information on the number of foods that are labeled as not genetically engineered.

(Comment 3) Numerous comments pointed out that mandatory labeling would have high costs for additional activities such as segregation, testing, labeling, quality control, and certification. One comment estimated that these costs could be as high as 6 to 17 percent of the farmgate price.

(Response) The paperwork reduction analysis only estimates the paperwork burden associated with voluntary labeling. The estimates related to mandatory labeling are outside the scope of the guidance, and we have not included them in the analysis.

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

Table 1.--Estimated Annual Recordkeeping Burden<sup>1</sup>

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping per the Guidance	85	4	340	1	340

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We have updated the number of recordkeepers and respondents to reflect new information on the number of food products that are labeled using the terms "biotechnology" and "GMO" (genetically modified organism) since the 2001 issuance of the 60-day notice and draft guidance. We estimate a recordkeeping burden, to retain paperwork to substantiate that the food or ingredient is produced without genetic engineering, only for products that are not also already labeled using the term "organic." We did not include products that are labeled "organic" in the estimated annual recordkeeping burden because, according to a final rule in the Federal Register of December 21, 2000 (65 FR 80548), issued by the Agriculture Marketing Service of the U.S. Department of Agriculture, a food labeled as "organic" would not be permitted to contain genetically engineered materials. Thus, there is no additional paperwork burden to substantiate a

claim that a product is not developed using genetic engineering for these certified organic products.

We based our revised estimates of the recordkeeping burden (table 1 of this document) on data from Labelbase by FoodEssentials. Labelbase is a custom online system for accessing a consumer packaged goods product data; the database contains more than 250,000 product labels that can be searched by keyword, ingredient, nutrient, allergen, label claim, or food additive, for example. Using this database, we have identified 540 food manufacturers who produce 2,160 products with the term "bioengineered" or "GMO" on their labels; this estimate includes manufacturers of human food and pet food. In addition, the National Center for Appropriate Technology's National Sustainable Agriculture Information Center maintains on its Web site a list of Organic Livestock Feed Suppliers. Using this list, we have identified 54 livestock feed suppliers that would be likely to include a statement about bioengineering on the label of their products and thus would have documentation to substantiate their claim.

Of the 2,160 human food and pet food products that we have identified as using the term "bioengineered" or "GMO" on their labels (presumably used in a context to designate foods that are not bioengineered), 1,140 of these products (285 manufacturers) also use the term "organic" on the label; 1,020 products do not use the term "organic" on the label ( $2,160 - 1,140 = 1,020$  products not organics;  $540 - 285 = 255$  manufacturers of not organic products). In addition, the 54 livestock feed suppliers are also organic producers, thus the 216 products attributed to these manufacturers already are considered to be labeled "organic." Thus, there are 1,020 products made by 255 human food and pet food manufacturers that would need to substantiate that their product or ingredient was not genetically engineered.

We estimate that the burden of maintaining the documentation is a one-time burden; the document to substantiate that the product or ingredient was produced without genetic engineering only needs to be generated once and then kept on file. To annualize this one-time burden, we divide by 3 because paperwork burden collections are approved on a 3-year cycle ( $255/3 = 85$ ). Thus, we estimate in table 1 that, on average, 85 manufacturers annually will collect and keep information that substantiates their label claim for four products ( $1,020 \text{ products}/3 = 340 \text{ products}/85 \text{ manufacturers} = 4 \text{ products per manufacturer}$ ).

We estimate this one-time recordkeeping burden to be 1 hour per product that makes use of a labeling claim which results in a burden of 1 hour for a total annualized recordkeeping burden of 340 hours ( $85 \text{ manufacturers} \times 4 \text{ records per manufacturer} \times 1 \text{ hour per record}$ ). In the 2001 notice, we estimated \$53,040 as "operating and maintenance costs" associated with this recordkeeping burden. These costs were reported in error and have been removed from table 1. We estimate no capital costs or operating and maintenance costs associated with this recordkeeping burden.

We do not estimate any reporting burden or third party disclosure burden associated with this information collection. Manufacturers who want to make use of this voluntary labeling claim option are considered to be those that already have such wording on their products' labels. We do not expect that this guidance will cause labels already in the marketplace to need to be reworded.

### III. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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