

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.

In the 1993 information request, we requested information on labeling of foods that have or have not been developed using bioengineering. Additionally, in 1999, we held three public meetings to get public input on our existing policy on the labeling of foods produced through biotechnology and the premarket review of such products. In response to comments that we received, we decided to develop

guidance for the voluntary labeling of foods indicating if they have or have not been developed using bioengineering. In the **Federal Register** of January 18, 2001 (66 FR 4839) FDA published a 60-day notice requesting public comment on the information collection provisions. The following is a discussion of the comments received and FDA's response to those comments.

Most of the comments agreed that labeling food products as bioengineered or nonbioengineered 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 nonbioengineered 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 bioengineered foods. Who should bear the paperwork burden is not within the scope of the guidance.

One comment stated that FDA underestimated the number of small firms that will choose to label their product as not bioengineered, but will not attempt to make an organic claim. 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 nonbioengineered claim. FDA's estimate of the number of products that would label their products with a bioengineered claim is based on the number of products making an organic claim and the number of products that are not currently making an organic claim on their label, but are making a statement about bioengineering on their Web site, through a press release, or other venue. The PRA analysis estimates the burden for the expected number of firms making bioengineered claims, however, if more firms choose to make bioengineered claims then the paperwork burden would be higher.

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 6–17 percent of the farmgate price. The paperwork reduction analysis only estimates the paperwork burden associated with voluntary labeling, and so does not dispute these estimates, but does not include them in the analysis.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

No. of Respondents	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Operating & Maintenance Costs	Total Hours
68	26	1,768	1	53,040	1,768

¹ There are no capital costs or operating and maintenance 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 nonorganic 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 bioengineered 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 nonorganic 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 nonbioengineering 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