

## 2018 SUPPORTING STATEMENT

### **National Bioengineered Food Disclosure Standard Under the Agricultural Marketing Act of 1946 Proposed Rule OMB No. 0581-NEW**

#### **A. Justification**

**1. EXPLAIN THE CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY. IDENTIFY ANY LEGAL OR ADMINISTRATIVE REQUIREMENTS THAT NECESSITATE THE COLLECTION.**

The U.S. Department of Agriculture (USDA) administers the Agricultural Marketing Act of 1946 (Title II of the Act of August 14, 1946). P.L. 114-216 amended the Agricultural Marketing Act of 1946, directing the Secretary of Agriculture to establish the National Bioengineered Food Disclosure Standard for disclosing any bioengineered food and any food that may be bioengineered. USDA is tasked with establishing requirements and procedures to carry out the new standard. P.L. 114-216 also addressed Federal preemption of State and local genetic engineering labeling requirements, and specifies that certification of food under USDA's National Organic Program (7 CFR 205) shall be considered sufficient to make claims about the absence of bioengineering in the food. USDA's Agricultural Marketing Service (AMS) is responsible for gathering industry input and conducting rulemaking on the proposed National Bioengineered Food Disclosure Standards. Publication of the proposed rule requests Office of Management and Budget approval on recordkeeping requirements. The proposed requirements and procedures will be codified at 7 CFR Part 66.

Foods covered by the proposed regulation are human foods and drinks and their respective components subject disclosure and labeling requirements in the Federal Food, Drug and Cosmetics Act (7 U.S.C. 301 et seq) and to certain food subject to labeling under three statutes administered by USDA's Food Safety Inspection Service (7 U.S.C. 1639 and 1639a): the Federal Meat Inspection Act (21 U.S.C. 601 et seq); the Poultry Products Inspection Act (21 U.S.C. 451 et seq); and the Egg Products Inspection Act (21 U.S.C. 1031 et seq).

**2. INDICATE HOW, BY WHOM, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED. EXCEPT FOR A NEW COLLECTION, INDICATE THE ACTUAL USE THE AGENCY HAS MADE OF THE INFORMATION RECEIVED FROM THE CURRENT COLLECTION.**

Persons required to maintain records would include food manufacturers, importers, retailers who label bulk foods or package and label foods for retail sale, and any other entities responsible for labeling for retail sale foods on AMS's bioengineered food lists. If a food is packaged prior to receipt by a retail establishment, either the food manufacturer or the importer would be responsible for ensuring that the food label bears a

bioengineered food disclosure in accordance with the regulation. If a retail establishment packages a food, then the retail establishment would be responsible for ensuring that the food bears a bioengineer food disclosure. Retailers would also be responsible for disclosure of food in bulk bins. AMS contends this approach aligns responsibility for labeling with that currently required under other mandatory food labeling laws and regulations, including those administered by the Food and Drug Administration and the Food Safety Inspection Service. The intent is to present meaningful disclosure to consumers who desire such information. The reporting burden also assures that all parties involved in supplying covered commodities to retail stores maintain and convey accurate information as required.

Disclosure with labeling requirement would be accomplished when a company affixes a symbol of sufficient size and clarity to appear prominently and conspicuously on the container. Companies meeting certain exemption criteria may choose to have text in place of a label to refer consumers to their website or phone number for information on the bioengineered nature of the product.

The audit process would involve access to records at the entity's place of business. AMS would examine the records during normal business hours to verify compliance with the standard's disclosure requirements. Under proposed §66.304(c), if an entity fails to provide AMS access to records, AMS would determine that the entity did not comply and would make the determination public. Companies would know the requirements through two future lists that AMS would maintain: (1) a list of bioengineered goods commercially available in the United States; and (2) a list of bioengineered foods with a high adoption rate that is commercially available in the United States, which is a subset of the first list. As set forth in proposed §66.300, recordkeeping applies to records for food on both lists of bioengineered foods. As set forth in §66.302(a)(3), records would have to be maintained for at least two years after the food's distribution for retail sale.

**3. DESCRIBE WHETHER, AND TO WHAT EXTENT, THE COLLECTION OF INFORMATION INVOLVES THE USE OF AUTOMATED, ELECTRONIC, MECHANICAL, OR OTHER TECHNOLOGICAL COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY, E.G. PERMITTING ELECTRONIC SUBMISSION OF RESPONSES, AND THE BASIS FOR THE DECISION FOR ADOPTING THIS MEANS OF COLLECTION. ALSO DESCRIBE ANY CONSIDERATION OF USING INFORMATION TECHNOLOGY TO REDUCE BURDEN.**

Entities covered by the regulation would be required to maintain customary and reasonable records part of current business practices, including, but not limited to, supply chain documents, purchase orders, sales confirmations, bills of lading, purchase receipts, written records, labels, contracts, brokers' statements, analytical testing results, and process certification that would substantiate claims about a food's bioengineering status. Entities required to keep such records would include food manufacturers, distributors, importers, retailers who label bulk foods or package and label foods for retail sale, and any other entities responsible for labeling retail foods and food products. Companies may select from a variety of disclosure methods to substantiate their claims, as long as

the records contain sufficient detail as to be readily understood and audited. Records would have to be maintained for at least two years after the food's distribution for retail sale, and could be in hardcopy or electronic form preferred by the individual company.

**4. DESCRIBE EFFORTS TO IDENTIFY DUPLICATION. SHOW SPECIFICALLY WHY ANY SIMILAR INFORMATION ALREADY AVAILABLE CANNOT BE USED OR MODIFIED FOR USE FOR THE PURPOSE(S) DESCRIBED IN ITEM 2 ABOVE.**

Records maintained in the normal course of business are acceptable for verifying bioengineering claims. The regulation would not require companies to create or duplicate records for this purpose, and does not conflict regulations administered by the Food and Drug Administration and other USDA program areas. The law prohibits the Secretary from requiring the creation of new records.

**5. IF THE COLLECTION OF INFORMATION IMPACTS SMALL BUSINESSES OR OTHER SMALL ENTITIES (ITEM 5 OF THE OMB FORM 83-1), DESCRIBE THE METHODS USED TO MINIMIZE BURDEN.**

AMS concludes that the proposed rule, if finalized, will have a significant economic impact on a substantial number of small entities. AMS intends to adopt a definition of small food manufacturer that would align with the Food and Drug Administration in an attempt to be consistent with similar regulations and minimize the cost burden on the industry. The total number of small businesses impacted is calculated to be 164,329, or 98 percent of 166,975 total firms. With the SBA definition of small agricultural service firms, the share of manufacturers now classified as small is at 96 percent (26,213 out of 27,176 total manufacturing firms).

Information collection requirements have been reduced to the minimum requirements possible. The primary sources of information used are readily available from normal business records maintained by manufacturers and importers. Such information can be supplied without data processing equipment or outside technical expertise. Thus, the information collection and reporting burden is relatively small, and requiring the same reporting requirements for all food manufacturers, distributors, importers and retail establishments does not significantly disadvantage any manufacturer or importer that is smaller than the industry average.

Small food manufacturers have an extra year for compliance. AMS intends that any final rule resulting from this rulemaking would become effective 60 days after the date of the final rule's publication in the Federal Register, with a compliance date of January 1, 2020, and with a delayed compliance date of January 1, 2021, for small food manufacturers.

**6. DESCRIBE THE CONSEQUENCE TO FEDERAL PROGRAM OR POLICY ACTIVITIES IF THE COLLECTION IS NOT CONDUCTED OR IS CONDUCTED LESS FREQUENTLY, AS WELL AS ANY TECHNICAL OR LEGAL OBSTACLES TO REDUCING BURDEN.**

On July 29, 2016, the President signed a bill that amends the Agricultural Marketing Agreement Act of 1946 to include Subtitle E, the National Bioengineered Food Disclosure Standard (Pub. L. 114-216). The law requires the Agency to establish a program that would require food manufacturers, retailers and other entities that label foods for retail sale to disclose information about bioengineered food and the bioengineered food ingredient content on food labels. Companies would demonstrate compliance during AMS's review of records companies maintain in either hardcopy or electronic format. No forms are being developed as a result of this regulations.

AMS is developing the regulation through rulemaking that includes publication of this proposed rule and then issuance of a final rule. In its role administering other labeling regulations, like National Organic Standards and Country of Origin Labeling, AMS is working to ensure consistency across these program to provide clarity and efficiency. Therefore, any further reduction in the burden imposed by this mandatory program would result in a program that would not achieve the objective of the authorizing legislation and could result in a program that would provide unverifiable and even misleading information to consumers.

**7. EXPLAIN ANY SPECIAL CIRCUMSTANCES THAT WOULD CAUSE AN INFORMATION COLLECTION TO BE CONDUCTED IN A MANNER:**

- **REQUIRING RESPONDENTS TO REPORT INFORMATION TO THE AGENCY MORE OFTEN THAN QUARTERLY;**

Companies would have five business days to provide records to AMS upon request. AMS would be required to provide notice of at least three days for onsite access to records

**DAYS**

- **REQUIRING RESPONDENTS TO PREPARE A WRITTEN RESPONSE TO A COLLECTION OF INFORMATION IN FEWER THAN 30 AFTER RECEIPT OF IT;**

- **REQUIRING RESPONDENTS TO SUBMIT MORE THAN AN ORIGINAL AND TWO COPIES OF ANY DOCUMENT;**

**AID,**

- **REQUIRING RESPONDENTS TO RETAIN RECORDS, OTHER THAN HEALTH, MEDICAL, GOVERNMENT CONTRACT, GRANT-IN-OR TAX RECORDS FOR MORE THAN 3 YEARS;**

AMS would require companies to maintain records that are already part of their course of doing business, including, but not limited to, supply chain documents, purchase orders, sales confirmations, bills of lading, purchase receipts, written records, labels, contracts, brokers' statements, analytical testing results, and process certification that would substantiate claims about a food's bioengineering status.

- **IN CONNECTION WITH A STATISTICAL SURVEY, THAT IS NOT**

**THAT DESIGNED TO PRODUCE VALID AND RELIABLE RESULTS  
CAN BE GENERALIZED TO THE UNIVERSE OF STUDY;**

- **REQUIRING THE USE OF A STATISTICAL DATA CLASSIFICATION  
THAT HAS NOT BEEN REVIEWED AND APPROVED BY OMB;**
- **THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT  
SUPPORTED BY AUTHORITY ESTABLISHED IN STATUE OR  
REGULATION, THAT IS NOT SUPPORTED BY  
DISCLOSURE AND DATA SECURITY POLICIES THAT ARE  
CONSISTENT WITH THE PLEDGE, OR WHICH  
UNNECESSARILY IMPEDES SHARING OF DATA WITH OTHER  
AGENCIES FOR COMPATIBLE CONFIDENTIAL USE; OR**
- **REQUIRING RESPONDENTS TO SUBMIT PROPRIETARY TRADE  
SECRET, OR OTHER CONFIDENTIAL INFORMATION UNLESS  
THE AGENCY CAN DEMONSTRATE THAT IT HAS INSTITUTED  
PROCEDURES TO PROTECT THE INFORMATION'S  
CONFIDENTIALITY TO THE EXTENT  
PERMITTED BY LAW.**

There are no other special circumstances. The collection of information is conducted in a manner consistent with the guidelines in 5 CFR 1320.6.

- 8. IF APPLICABLE, PROVIDE A COPY AND IDENTIFY THE DATE AND PAGE  
NUMBER OF PUBLICATION IN THE FEDERAL REGISTER OF THE  
AGENCY'S NOTICE, REQUIRED BY 5 CFR 1320.8(d), SOLICITING  
COMMENTS ON THE INFORMATION COLLECTION PRIOR TO  
SUBMISSION TO OMB. SUMMARIZE PUBLIC COMMENTS RECEIVED IN  
RESPONSE TO THAT NOTICE AND DESCRIBE ACTIONS TAKEN BY THE  
AGENCY IN RESPONSE TO THESE COMMENTS. SPECIFICALLY ADDRESS  
COMMENTS RECEIVED ON COST AND HOUR BURDEN.**

AMS published a proposed rule in the Federal Register on May 4, 2018, Vol. 83, No. 87, Pages 19860-19889. A 60-day notice on the information collection is imbedded in the proposed rule.

- **DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE  
AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY  
OF DATA, FREQUENCY OF COLLECTION, THE CLARITY OF  
INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE,  
OR REPORTING FORMAT (IF ANY), AND ON THE DATA  
ELEMENTS TO BE RECORDED, DISCLOSED, OR REPORTED.**
- **CONSULTATION WITH REPRESENTATIVES OF THOSE FROM  
WHOM INFORMATION IS TO BE OBTAINED OR THOSE WHO  
MUST COMPILE RECORDS SHOULD OCCUR AT LEAST ONCE**

**EVERY 3 YEARS -- EVEN IF THE COLLECTION OF INFORMATION ACTIVITY THERE MAY BE PRECLUDE CONSULTATION IN A CIRCUMSTANCES SHOULD BE**

**IS THE SAME AS IN PRIOR PERIODS. CIRCUMSTANCES THAT MAY SPECIFIC SITUATION. THESE EXPLAINED.**

This proposed rule presents AMS's proposed requirements and procedures for the National Bioengineered Food Disclosure Standard to be codified at 7 CFR part 66.

**9. EXPLAIN ANY DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS, OTHER THAN REMUNERATION OF CONTRACTORS OR GRANTEES.**

No payments or gifts are provided to respondents.

**10. DESCRIBE ANY ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS AND THE BASIS FOR THE ASSURANCE IN STATUTE, REGULATION, OR AGENCY POLICY.**

Company records and information contained in them that AMS reviews for compliance purposes would be used only by authorized USDA personnel, and would be maintained confidential to prevent inadvertent release. AMS would review the records during audits and examinations, as appropriate, to verify compliance with the standard's disclosure requirements. Proprietary business information, including product formulations and recipes, would be kept confidential by USDA, consistent with the Freedom of Information Act, 5 U.S.C. 552 et seq.

**11. PROVIDE ADDITIONAL JUSTIFICATION FOR ANY QUESTIONS OF A SENSITIVE NATURE, SUCH AS SEXUAL BEHAVIOR AND ATTITUDES, RELIGIOUS BELIEFS, AND OTHER MATTERS THAT ARE COMMONLY CONSIDERED PRIVATE. THIS JUSTIFICATION SHOULD INCLUDE THE REASONS WHY THE AGENCY CONSIDERS THE QUESTIONS NECESSARY, THE SPECIFIC USES TO BE MADE OF THE INFORMATION, THE EXPLANATION TO BE GIVEN TO PERSONS FROM WHOM THE INFORMATION IS REQUESTED, AND ANY STEPS TO BE TAKEN TO OBTAIN THEIR CONSENT.**

There are no questions of a sensitive nature in this information collection. Business records that AMS would review include standard documents created in the course of the companies doing business, including purchase orders, sales confirmations, bills of lading, purchase receipts, written records, labels, contracts, brokers' statements, analytical testing results, and process certification that would substantiate claims about a food's bioengineering status.

The response to Question 3 described AMS's two lists under development that will be used in the process of determining whether a regulated entity needs to disclose under the National Bioengineered Food Disclosure Standard. The lists are intended to enhance

clarity for domestic entities and foreign-based importers needing to comply. The public would petition or request AMS to consider changes to the lists. Proposed §66.204 describes how a person would make a petition and would prescribe how AMS would properly mark confidential business information that may be included to support the request.

**12. PROVIDE ESTIMATES OF THE HOUR BURDEN OF THE COLLECTION OF INFORMATION. THE STATEMENT SHOULD:**

**- INDICATE THE NUMBER OF RESPONDENTS, FREQUENCY OF RESPONSE, ANNUAL HOUR BURDEN, AND AN EXPLANATION OF HOW THE BURDEN WAS ESTIMATED. UNLESS DIRECTED TO DO SO, AGENCIES SHOULD NOT CONDUCT SPECIAL SURVEYS TO OBTAIN INFORMATION ON WHICH TO BASE HOUR BURDEN ESTIMATES. CONSULTATION WITH A SAMPLE (FEWER THAN 10) OF POTENTIAL RESPONDENTS IS DESIRABLE. IF THE HOUR BURDEN ON RESPONDENTS IS EXPECTED TO VARY WIDELY BECAUSE OF DIFFERENCE IN ACTIVITY, SIZE, OR COMPLEXITY, SHOW THE RANGE OF ESTIMATED HOUR BURDEN, AND EXPLAIN THE REASONS FOR THE VARIANCE. GENERALLY, ESTIMATES SHOULD NOT INCLUDE BURDEN HOURS FOR CUSTOMARY AND USUAL BUSINESS PRACTICES.**

**- IF THIS REQUEST FOR APPROVAL COVERS MORE THAN ONE FORM, PROVIDE SEPARATE HOUR BURDEN ESTIMATES FOR EACH FORM AND AGGREGATE THE HOUR BURDENS IN OF OMB FORM 83-I.**

**ITEM 13**

Estimates of the recordkeeping burden have been summarized on the AMS-71 form. This submission reflects a total of 166,975 respondents for 6,845,975 burden hours for one-time paperwork costs and 239,913 recordkeepers for 1,127,591 burden hours for ongoing recordkeeping costs on an annual basis. The respondents' estimated annual cost of complying with the regulation is \$269.27 million. This estimated total is calculated by multiplying 7,973,566 (total burden hours) by \$33.77, the national mean hourly rate contained in the National Compensation Survey: Occupational Employment and Wages, May 2016, published by the Bureau of Labor Statistics ([https://www.bls.gov/oes/2016/may/oes\\_stru.htm](https://www.bls.gov/oes/2016/may/oes_stru.htm))

**- PROVIDE ESTIMATES OF ANNUALIZED COST TO RESPONDENTS FOR THE HOUR BURDENS FOR COLLECTIONS OF INFORMATION, IDENTIFYING AND USING APPROPRIATE WAGE RATE CATEGORIES.**

In general, the supply chain for each of the covered commodities includes food manufacturers, importers and retailers that label food for retail sale. Exempt outlets include cafeterias, restaurants, lunch rooms, food stands, saloons, taverns, bars, lounges, salad

bars, delicatessens and other food enterprises located within retail establishments that provide ready-to-eat meals.

USDA is issuing this rule in conformance with Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, which include potential economic, environmental, public health and safety effects, distributive impacts, and equity. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

As indicated in the proposed rule, USDA estimates that the costs of the proposed National Bioengineered Food Disclosure Standard would range from \$598 million to \$3.5 billion for the first year, with ongoing annual costs of between \$114 million and \$225 million. The annualized costs in perpetuity would be \$132 million to \$330 million at a three percent discount rate and \$156 million to \$471 million at a seven percent discount rate. These results assume that the final rule includes a provision for the use of existing label inventories that extends to January 1, 2022; without such a provision, the total annualized cost are \$164 million to \$410 million and \$236 million to \$559 million at discount rates of three and seven percent respectively.

These cost estimates represent the cost of the proposed standard relative to a baseline in which there are no requirements for the labeling of food containing bioengineered foods or ingredients. This estimate encompasses three options for the definition of very small food manufacturers: less than \$2.5 million annual receipts (proposed definition); less than \$500,000 annual receipts (alternative A); and less than \$5 million annual receipts (alternative B). Very small food manufacturers are exempted from the regulation, which utilizes the definition of small food manufacturers to mean any food manufacturer with less than \$10 million in annual receipts but \$2.5 million or more in annual receipts. Small food manufacturers have an extra year for compliance. This cost estimate also includes three thresholds for separation costs: not more than 5 percent of a specific ingredient by weight and only inadvertent introduction allowed; not more than 0.9 percent of a specific ingredient by weight and only inadvertent introduction allowed; and, a threshold of less than 5 percent of total additive weight. This estimate includes costs of disclosure for highly refined foods (such as oils and sugars) with no detectable rDNA. This estimate excludes the costs of disclosure for incidental additives.

The affected firms will broadly incur two types of costs. First, newly established firms will incur initial or start-up costs to comply with the rule establishing a record keeping system. Initial costs will be borne by each firm, even though a single firm may operate more than one establishment. Second, firms will incur additional recordkeeping costs associated with storing and maintaining records on an ongoing basis. These activities will take place in each establishment operated by each affected business.

#### *Initial Recordkeeping Costs*

With respect to initial recordkeeping costs, it is believed that most manufacturers, retailers and importers maintain many of the types of records that would be needed to

substantiate labeling claims. Entities starting operations will incur some additional incremental costs to record, maintain, and transfer pertinent records. Examples of initial or start-up costs would be any additional recordkeeping burden needed to record the required bioengineered and, if applicable, method of production information and transfer this information to handlers, processors, wholesalers, or retailers via records used in the normal course of business.

Companies will need an estimated 4 hours to modify an established system for organizing records to carry out the purposes of this regulation. This additional time would be required to modify existing recordkeeping systems to incorporate any added information needed to substantiate claims. Proposed § 66.5(e) would exempt certified organic foods from bioengineered disclosure, so food manufacturers, retailers, and importers of certified organic food would not be required to maintain additional records to demonstrate that the organic food is not bioengineered for purpose of the National Bioengineered Food Disclosure Standard regulations.

Under the proposed rule, importers would be subject to the same disclosure and compliance requirements as domestic entities. Generally, importers of foods on either AMS list of commercially available bioengineered foods would be required to make appropriate disclosures on the labels of bioengineered foods and would be required to verify, with appropriate records, that imported foods on the lists that do not bear disclosures are not bioengineered. However, to facilitate international trade, AMS would consider establishing recognition arrangements with appropriate foreign government entities that have established labeling standards for bioengineered food. Such an arrangement would allow importers to sell products in the United States that comply with the source nation's labeling standard for bioengineered food, and therefore the National Bioengineered Food Disclosure Standard. For that reason, importers are not part of the burden calculation.

**13. PROVIDE AN ESTIMATE OF THE TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORDKEEPERS RESULTING FROM THE COLLECTION OF INFORMATION. (DO NOT INCLUDE THE COST OF ANY HOUR BURDEN SHOWN IN ITEMS 12 AND 14).**

**- THE COST ESTIMATE SHOULD BE SPLIT INTO TWO COMPONENTS: (a) A TOTAL CAPITAL AND START-UP COST COMPONENT (ANNUALIZED OVER ITS EXPECTED USEFUL LIFE); AND (b) A TOTAL OPERATION AND MAINTENANCE AND PURCHASE OF SERVICES COMPONENT. THE ESTIMATES SHOULD TAKE INTO ACCOUNT COSTS ASSOCIATED WITH GENERATING, MAINTAINING, AND DISCLOSING OR PROVIDING THE INFORMATION. INCLUDE DESCRIPTIONS OF METHODS USED TO ESTIMATE MAJOR COST FACTORS INCLUDING SYSTEM AND TECHNOLOGY ACQUISITION, EXPECTED USEFUL LIFE OF CAPITAL EQUIPMENT, THE DISCOUNT RATE(S), AND THE TIME PERIOD OVER WHICH COSTS WILL BE INCURRED. CAPITAL**

**AND START-UP COSTS INCLUDE, AMONG OTHER ITEMS, PREPARATIONS FOR COLLECTING INFORMATION SUCH AS PURCHASING COMPUTERS AND SOFTWARE; MONITORING, SAMPLING, DRILLING AND TESTING EQUIPMENT; AND RECORD STORAGE FACILITIES.**

**- IF COST ESTIMATES ARE EXPECTED TO VARY WIDELY, AGENCIES SHOULD PRESENT RANGES OF COST BURDENS AND EXPLAIN THE REASONS FOR THE VARIANCE. THE COST OF PURCHASING OR CONTRACTING OUT INFORMATION COLLECTION SERVICES SHOULD BE A PART OF THIS COST BURDEN ESTIMATE. IN DEVELOPING COST BURDEN ESTIMATES, AGENCIES MAY CONSULT WITH A SAMPLE OF RESPONDENTS (FEWER THAN 10), UTILIZE THE 60-DAY PRE-OMB SUBMISSION PUBLIC COMMENT PROCESS AND USE EXISTING ECONOMIC OR REGULATORY IMPACT ANALYSIS ASSOCIATED WITH THE RULEMAKING CONTAINING THE INFORMATION COLLECTION, AS APPROPRIATE.**

**- GENERALLY, ESTIMATES SHOULD NOT INCLUDE PURCHASES OF EQUIPMENT OR SERVICES, OR PORTIONS THEREOF, MADE: (1) PRIOR TO OCTOBER 1, 1995, (2) TO ACHIEVE REGULATORY COMPLIANCE WITH REQUIREMENTS NOT ASSOCIATED WITH THE INFORMATION COLLECTION, (3) FOR REASONS OTHER THAN TO PROVIDE INFORMATION OR KEEPING RECORDS FOR THE GOVERNMENT, OR (4) AS PART OF CUSTOMARY AND USUAL BUSINESS OR PRIVATE PRACTICES.**

In the 60-day notice, USDA estimates that the costs to industry implementing the proposed National Bioengineered Food Disclosure Standard would range from \$598 million to \$3.5 billion for the first year. This total accounts for segregating inventory, calibrating machinery, and modifying other business processes.

**14. PROVIDE ESTIMATES OF ANNUALIZED COST TO THE FEDERAL GOVERNMENT. ALSO, PROVIDE A DESCRIPTION OF THE METHOD USED TO ESTIMATE COST, WHICH SHOULD INCLUDE QUANTIFICATION OF HOURS, OPERATION EXPENSES (SUCH AS EQUIPMENT, OVERHEAD, PRINTING, AND SUPPORT STAFF), AND ANY OTHER EXPENSE THAT WOULD NOT HAVE BEEN INCURRED WITHOUT THIS COLLECTION OF INFORMATION. AGENCIES ALSO MAY AGGREGATE COST ESTIMATES FROM ITEMS 12, 13, AND 14 IN A SINGLE TABLE.**

The Federal government's annual costs for providing oversight and assistance for this information collection is estimated at \$53,000 the first year, and \$54,590 for subsequent years, assuming higher overhead costs. A breakdown of the oversight costs for the first

year is the following:

Salaries/benefits/awards	\$25,000
Travel	\$5,000
Printing/Copying/Mailing/ Postage	\$1,400
Federal Register Services	\$2,400
OGC (legal services)	\$16,000
Supplies/equipment	\$3,200
TOTAL	\$53,000

**15. EXPLAIN THE REASON FOR ANY PROGRAM CHANGES OR ADJUSTMENTS REPORTED IN ITEMS 13 OR 14 OF THE OMB FORM 83-I.**

This is a new collection.

**16. FOR COLLECTIONS OF INFORMATION WHOSE RESULTS WILL BE PUBLISHED, OUTLINE PLANS FOR TABULATION, AND PUBLICATION. ADDRESS ANY COMPLEX ANALYTICAL TECHNIQUES THAT WILL BE USED. PROVIDE THE TIME SCHEDULE FOR THE ENTIRE PROJECT, INCLUDING BEGINNING AND ENDING DATES OF THE COLLECTION OF INFORMATION, COMPLETION OF REPORT, PUBLICATION DATES, AND OTHER ACTIONS.**

Information obtained under this information collection is not published.

**17. IF SEEKING APPROVAL TO NOT DISPLAY THE EXPIRATION DATE FOR OMB APPROVAL OF THE INFORMATION COLLECTION, EXPLAIN THE REASONS THAT DISPLAY WOULD BE INAPPROPRIATE.**

There is no form submission requirement associated with this collection.

**18. EXPLAIN EACH EXCEPTION TO THE CERTIFICATION STATEMENT IDENTIFIED IN ITEM 19, "CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS," OF OMB FORM 83-I.**

The Agency is able to certify compliance with all provisions under Item 19 of OMB Form 83-I.

**B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

This information collection does not employ statistical methods.