

2018 SUPPORTING STATEMENT

National Bioengineered Food Disclosure Standard Under the Agricultural Marketing Act of 1946 Final Rule OMB No. 0581-0315

Note: The Agricultural Marketing Service's (AMS) calculations on the recordkeeping burden are updated from its initial submission to OMB during the proposed rule stage. The number of respondents no longer includes small businesses that are exempt from the regulations. The number of respondents now includes importing entities that are included in total of number of manufacturers in the supplementary AMS-71 spreadsheet, along with domestic manufacturers. AMS modified its estimate for annual responses and total burden hours to match numbers contained in the Regulatory Impact Analysis in the final rule.

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 certain foods that are bioengineered or contain bioengineered ingredients. The final rule fulfills USDA's need to establish 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) were considered sufficient to make claims about the absence of bioengineering in the food. AMS gathered industry input and conducted rulemaking on the National Bioengineered Food Disclosure Standards. Publication of the proposed rule on May 4, 2018, informed the public of AMS's intent to request Office of Management and Budget (OMB) approval on recordkeeping requirements. The proposed requirements and procedures will be codified in 7 CFR Part 66.

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.

Foods covered by the 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 include food manufacturers and importers, and any other entities responsible for labeling for retail sale foods on AMS's bioengineered food list. 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.

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 must ensure that the food bears a bioengineer food disclosure. Retailers are 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 is 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 involves 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 a list that AMS will maintain containing bioengineered crops and foods that may be produced in other countries. As set forth in proposed §66.300, recordkeeping applies to records for food on the list 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 are 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 are 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 have to be maintained for at least two years after the food's distribution for retail sale, and could be in hardcopy or an electronic format 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 does not require companies to create or duplicate records for this purpose, and does not conflict with regulations administered by the Food and Drug Administration and other USDA program areas.

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 regulation will not have a significant economic impact on a substantial number of small entities. Nevertheless, the regulation will affect a large number of small entities. The total number of small businesses under the Small Business Administration definition of small that could be impacted is calculated to be 164,329, or 98 percent of 166,975 total firms. However, some of these firms are more likely to be affected than others. For example, grocery stores are more likely to sell fresh produce covered by the labeling requirement than beer and liquor stores even though both are included in the numbers cited above.

For purposes of both the Regulatory Impact Analysis and this Information Collection Request, AMS is focusing on those firms most likely to face direct costs associated with

the regulation. The number of total entities potentially affected by the rule are the 89,175 manufacturers (both foreign and domestic) registered with the FDA in 2016 and the 68,839 grocery and fresh fruit and vegetable stores according to the 2012 Statistics of U.S. Business (SUSB).

The regulation includes a one-year compliance extension for “small food manufacturers.” AMS adopted a definition of “small food manufacturer” (food (and dietary supplement) manufacturers with receipts less than \$10 million per year) that aligns with the Food and Drug Administration to be consistent with similar regulations and minimize the cost burden on the industry. Because of this provision, 73,125 of the 89,175 food manufacturers potentially covered by the rule will have an extra year to comply with the regulation. 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.

In addition, the regulation completely exempts “very small food manufacturers” (defined as manufacturers with annual receipts less than \$2,500,000). This exempts 66,881 of the 89,175 food manufacturers that would have been covered absent the exemption.

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.

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 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 developed 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 worked to ensure consistency across these programs 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;**

The proposed rule offered the public opportunity to comment on AMS's proposed five- and three-day timeframes to produce records and access to records at a place of business. AMS determined in the final rule that companies have five business days to provide records to AMS upon request, and AMS is 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 DAYS 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 requires 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.

THAT

- **IN CONNECTION WITH A STATISTICAL SURVEY, THAT IS NOT DESIGNED TO PRODUCE VALID AND RELIABLE RESULTS THAT 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;**

DISCLOSURE AND CONSISTENT WITH THE UNNECESSARILY IMPEDES SHARING OF

- **THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT SUPPORTED BY AUTHORITY ESTABLISHED IN STATUE OR REGULATION, THAT IS NOT SUPPORTED BY**

DATA SECURITY POLICIES THAT ARE PLEDGE, OR WHICH DATA WITH OTHER

AGENCIES FOR COMPATIBLE CONFIDENTIAL

USE; OR

Under § 66.200 of the final regulation, the determination process begins with the submission of a request or petition submitted by an individual to AMS for determination regarding factors and conditions under which a food is considered a bioengineered food. Section § 66.204 describes the process for submitting a request or petition, including where to send the submission. The submission needs to include a description and analysis of the requested new factor or condition and any supporting document or data. Section § 66.204 describes how to properly mark confidential business information that may be included to support the request, to ensure its confidentiality. Finally, § 66.204 instructs that the submission must explain how the standards for consideration apply to the requested factor or condition.

- THE**
- **REQUIRING RESPONDENTS TO SUBMIT PROPRIETARY TRADE SECRET, OR OTHER CONFIDENTIAL INFORMATION UNLESS 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. Most of the 14,016 public comments AMS received on the proposed regulation by the July 3, 2018, due date were equivalent to form letters or similarly worded. Comments pertaining to recordkeeping burden totaled 111, while comments pertaining to recordkeeping requirements totaled 76.

In general, comments in response to the proposed recordkeeping requirements in the Notice of Proposed Rulemaking supported AMS's proposals. Commenters agreed that recordkeeping requirements of the National Bioengineered Food Disclosure Standard should be consistent with those under other AMS marketing programs so as not to present an unreasonable burden to entities who must comply with the standard. Commenters observed that the recordkeeping requirements as proposed would probably not impose additional costs or burdens to existing business practices. Commenters provided

examples of typical records generated in the course of business that should satisfy the audit requirements under § 66.402 to verify compliance with disclosure requirements under the National Bioengineered Food Disclosure Standard. Commenters suggested that the regulation include examples of appropriate records an entity might maintain to meet the recordkeeping requirements. Commenters supported the proposed flexibility that would allow for record maintenance in the format preferred by the entity. Commenters also supported the proposed two-year record retention period, consistent with the recordkeeping requirements under other Department of Agriculture and Food and Drug Administration regulations.

AMS agrees that recordkeeping and compliance requirements under the National Bioengineered Food Disclosure Standard should be consistent with those under other AMS programs, such as the National Organic Program, Country of Origin Labeling Program, and the Perishable Agricultural Commodities Act, and has incorporated elements from each of those programs into the National Bioengineered Food Disclosure Standard. Accordingly, § 66.302 does not specify the records regulated entities must maintain to demonstrate compliance with the disclosure regulations. Instead, as with other AMS programs, regulated entities are free to determine for themselves which of their customary business records will demonstrate compliance and should be maintained. Section 66.302(a)(4) includes a non-exhaustive list of records that could satisfy the recordkeeping requirements of the National Bioengineered Food Disclosure Standard. That list includes: supply chain records, bills of lading, invoices, supplier attestations, labels, contracts, brokers' statements, third party certifications, laboratory testing results, validated process verifications, and other records generated or maintained by the regulated entity in the normal course of business. Section 66.302(a)(2) provides that records can be in paper or electronic format at the discretion of the regulated entity. Section 66.302(a)(3) requires that records be maintained for at least two years beyond the date the food or food product is sold or distributed for retail sale.

Section 66.302(b) provides that the regulated entity must maintain records related to foods that are on AMS's List of Bioengineered Foods. As discussed above, the information in the records determines whether a bioengineering disclosure is required and the content of the disclosure ("bioengineered" versus "contains bioengineered food ingredient"). For a food or food ingredient that is not on the AMS list, but for which the regulated entity has actual knowledge that the food or food ingredient is bioengineered, the regulated entity must maintain records for that food or food ingredient.

Some comments in response to the Notice of Proposed Rulemaking opposed requiring entities who do not handle bioengineered foods to maintain records to verify compliance with the regulation. Other comments supported AMS's proposal to do so, explaining that all regulated entities subject to the disclosure standard should be required to keep the same kind of records. AMS agrees that all food manufacturers, importers, and retailers who offer for retail sale foods on the List of Bioengineered Foods are considered regulated entities for purposes of the National Bioengineered Food Disclosure Standard insofar as they may be required to make bioengineered food disclosures. Their customary business records should be able to satisfy an audit to determine whether they are in compliance with the disclosure requirements of the National Bioengineered Food

Disclosure Standard.

The amended Act requires each person subject to the disclosure requirements of the National Bioengineered Food Disclosure Standard to give the Secretary access to records to establish compliance with the disclosure requirements upon request. Accordingly, § 66.304 sets forth the provisions for AMS's access to records.

AMS proposed in the Notice of Proposed Rulemaking that entities would have five business days to provide records to AMS upon request, unless AMS extends the deadline. AMS also proposed to provide prior notice of at least three business days if we need to access the records at the entity's place of business. Finally, AMS proposed that it would examine the records during normal business hours and that entities should make their records available during those times.

Commenters generally supported the proposed five- and three-day timeframes to produce records and access to records at the entity's place of business, respectively. Some commenters suggested that because the National Bioengineered Food Disclosure Standard is a marketing standard rather than a food safety regulation, longer timeframes for records production would be appropriate. AMS believes that the timelines for records production and access are appropriate for enforcing compliance with the National Bioengineered Food Disclosure Standard and notes that flexibility is provided in the regulation to extend deadlines if necessary. Commenters requested that regulated entities be allowed to maintain records at locations most convenient for each business. AMS agrees that entities can maintain records at the location that best serves the entity's business needs.

Accordingly, § 66.304(a) provides that the entity must provide records to AMS within five business days of AMS's request, unless AMS extends the deadline. Section 66.304(b) provides that AMS will give at least three business days' notice if it needs access to records at the entity's place of business. As well, AMS will examine records during normal business hours, and records should be made available during those times. Finally, entities must provide AMS access to facilities necessary for records examinations. As proposed in the Notice of Proposed Rulemaking, § 66.304(c) specifies that if an entity fails to give AMS access to records as required, the result of the examination or audit will be that the entity did not comply with the requirement to provide access to records and that AMS could not confirm whether the entity is in compliance with the disclosure standard of the National Bioengineered Food Disclosure Standard.

- **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**

MUST EVERY 3 INFORMATION ACTIVITY THERE MAY BE PRECLUDE CONSULTATION IN A CIRCUMSTANCES SHOULD BE **WHOM INFORMATION IS TO BE OBTAINED OR THOSE WHO COMPILE RECORDS SHOULD OCCUR AT LEAST ONCE YEARS -- EVEN IF THE COLLECTION OF IS THE SAME AS IN PRIOR PERIODS. CIRCUMSTANCES THAT MAY SPECIFIC SITUATION. THESE EXPLAINED.**

This final rule on labeling and recordkeeping requirements and procedures for the National Bioengineered Food Disclosure Standard will 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 will be used only by authorized USDA personnel, and will 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, will 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 2 on Page 2 above described AMS's "List of Bioengineered

Foods” that will be used in the process of determining whether a regulated entity needs to disclose under the National Bioengineered Food Disclosure Standard. The list is 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 list. How a person will make a petition and how AMS will properly mark confidential business information to be included to support the request is described in §66.204 of the final regulation. That section specifies marked “Confidential Business Information” with redacted text.

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 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**
ITEM 13 OF OMB FORM 83-I.

Estimates of the recordkeeping burden have been summarized on the AMS-71 form. This submission reflects a total of 22,372 respondents for 20,307,573 burden hours for each of the first three years for one-time paperwork costs and 91,133 record-keepers for 205,147 burden hours for ongoing recordkeeping costs on an annual basis. The respondents’ estimated annual cost of complying with the regulation is \$692.71 million. This estimated total is calculated by multiplying 20,512,720 (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).

- **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.

USDA estimates that the costs of the proposed National Bioengineered Food Disclosure Standard would range from \$569 million to \$3.9 billion for the first year, with ongoing annual costs of between \$51 million and \$117 million. The annualized costs in perpetuity would be \$68 million to \$234 million at a three-percent discount rate and \$91 million to \$391 million at a seven-percent discount rate. 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.

The affected firms will broadly incur two types of costs. First, 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 Costs

In the first years of the program, affected firms will incur costs associated with determining which of their products are potentially covered, developing a compliance approach for each product including the possibility of replacing bioengineered ingredients with non-bioengineered equivalents, and designing a record system to support the regulatory approach. These costs will be incurred by both manufacturers and retailers, but to different degrees.

There are 7,431 manufacturers that will be incur these costs. This includes both foreign and domestic manufacturers, but excludes all manufacturers covered under the definition of very small food manufacturer. For purposes of calculating an annual burden we assume that one third of the affected firms come into compliance in each of the first three years. Firms will incur these startup costs for each unique product formulation. Using the Food and Drug Administration's labeling database and adjusting the number of products to account for organic/non-GMO products and products produced by very small food manufacturers, we estimate that covered firms have 26 unique formulas on average. Developing the information necessary to demonstrate compliance for each product is

estimated to take 100 hours. This results in annual burden to manufacturers of 19,321,467 hours for each of the first three years.

Retailers face a lower burden because they are only required to disclose information on bioengineered products sold in bulk, such as certain types of fresh produce. We assume that designing compliance will occur at the corporate level (rather than at each individual store). There were 44,823 firms in the 2012 SUSB in the grocery and fresh fruit and vegetable store NAICS codes. Again, we divide this total by three to annualize the burden over the initial three year approval period. Not all firms will sell all potentially covered products. So, we assume that each firm will need to develop plans for two products. Each such plan is assumed to take 33 hours to develop. This results in an annual burden estimate of 986,106 hours for each of the first three years of the program.

Recordkeeping Costs

With respect to 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.

Each of the 22,294 manufacturers will need an estimated average 2.1 hours to track compliance of all products that comply through replacement of ingredients rather than through labeling. This annual burden of 46,817 hours would be necessary 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.

We assume that recordkeeping to demonstrate compliance by retailers will take place at the store level. There were 68,839 establishments reported in the SUSB in 2012. The average burden to these establishments is 2.3 hours, resulting in a total burden to retailers of 158,330 hours.

Importers are subject to the same disclosure and compliance requirements as domestic entities. Importers of foods on AMS's List of Bioengineered Foods are required to make appropriate disclosures on the labels of bioengineered foods and to verify, with appropriate records, that imported foods on the list that do not bear disclosures are not bioengineered. As a result, all estimates of manufacturers include both domestic and foreign manufacturers.

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**

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 addition to the burden to affected entities in creating and maintaining the information necessary to demonstrate compliance, the regulation requires reporting of this information to the public. This reporting takes place through labeling and signage of products that meet the definition of a bioengineered food. These labels largely represent expenditures of firms' non-labor resources (i.e. money). These costs are considered part of the initial cost of the rule and

averaged over the three years of the approval.

These costs are estimated to range from \$63 million to \$209 million over the first three years or, \$21 million to \$70 million per year.

The regulation will also result in expenditures of resources to test ingredients to determine or prove their bioengineered status under the regulations. These costs may be borne by manufacturers or by suppliers who are not regulated by the standard. As a result, we treat these testing costs as both an initial and ongoing monetary cost of the standard (rather than as a labor cost to affected entities). These costs occur each year the ICR is in effect and are estimated to range from \$0 to \$59 million each year.

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. AMS modified burden estimates throughout the proposed and final rulemaking processes to ensure they match the scope of the regulations as accurately as possible. That includes AMS modifying its estimate for annual responses and total burden hours to match numbers contained in the Regulatory Impact Analysis in the final rule, as indicated in the “Note” section at the top of this Supporting Statement.

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.