2022 SUPPORTING STATEMENT

National Bioengineered Food Disclosure Standard
Under the Agricultural Marketing Act of 1946

OMB No. 0581-0315

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 fulfils 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 requirements and procedures are codified in 7 CFR Part 66.

USDA issued 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 bioengineered 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 symbol 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 §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 §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 retails 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 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 168,129, or 98 percent of 171560 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 13,865 manufacturers (both foreign and domestic) and the 138,537 grocery and fresh fruit and vegetable stores, wholesalers, and vitamin/supplement retailers according to the 2017 Statistics of U.S. Business (SUSB).

In addition, the regulation completely exempts "very small food manufacturers" (defined as manufacturers with annual receipts less than $2,500,000). This exempts 23,350 of the 37,215 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 regulation.

AMS developed the regulation through rulemaking that includes 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;**

  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.

- **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;

- **REQUIRING RESPONDENTS TO RETAIN RECORDS, OTHER THAN HEALTH, MEDICAL, GOVERNMENT CONTRACT, GRANT-IN-AID, 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.

- **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;**

- **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**

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.

- **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.

As required by 5 CFR 1320.8(d) a 60-day notice for comments was published in the Federal Register on February 22, 2022, Vol. 87, No. 35, page 9564. No substantive comments were received.

- 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 IS THE SAME AS IN PRIOR PERIODS. THERE MAY BE CIRCUMSTANCES THAT MAY PRECLUDE CONSULTATION IN A SPECIFIC SITUATION. THESE CIRCUMSTANCES SHOULD BE EXPLAINED.

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 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 ITEM 13 OF OMB FORM 83-I.**

Estimates of the recordkeeping burden have been summarized on the AMS-71 form. Estimates were calculated using the 2017 Statistics of US Businesses (SUSB) (https://www.census.gov/data/datasets/2017/econ/susb/2017-susb.html). This data contains information on enterprise size in both number of employees and average annual receipts and organizes this information using six digit North American Industry Classification System (NAICS) codes. For the purposes of this information collection NAICS codes relating to food manufacturing, retailers, and wholesale retailers were considered to accurately represent the regulated entities affected by the Standard. This submission reflects a total 155,098 record-keepers for 353,952.40 burden hours for ongoing recordkeeping costs on an annual basis. The respondents' estimated annual cost of complying with the regulation is $13.2 million. This estimated total is calculated by multiplying 353,952.40 (total burden hours) by $37.38, the national mean hourly rate for 41-4010 Sales Representatives, Wholesale and Manufacturing contained in the National Compensation Survey: Occupational Employment and Wages, May 2021, published by the Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#41-0000).

- **PROVIDE ESTIMATES OF ANNUALIZED COST TO RESPONDENTS FOR THE HOURs 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 retails 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 issued 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.

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 incurred 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 were incurred by both manufacturers and retailers, but to different degrees. In subsequent years, after the mandatory compliance date has passed, there will be no additional start-up expenses unless the AMS List of Bioengineered Foods is updated to include additional foods. For the purposes of this collection, no additional foods have been added to the List and therefore, no initial costs will be incurred by any regulated entities.

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. Table 1 below lists the NAICS Codes for food manufacturers considered for this collection and the number of establishments with recordkeeping requirements.

Table 1: List of NAICS codes, code meaning, and number of establishments considered for this information collection for food manufacturers.

2012 NAICS code	Meaning of 2012 NAICS code	Number of Establishments			
		Total	Small	Large	Less than 2.5 million
311211	Flour Milling	340	175	165	57
311212	Rice Milling	78	27	51	7
311213	Malt Manufacturing	42	19	23	19
311221	Wet Corn Milling	73	17	56	11
311224	Soybean and Other Oilseed Processing	175	19	156	26
311225	Fats and Oils Refining and Blending	103	12	91	15
311230	Breakfast Cereal Manufacturing	85	18	67	29
311313	Beet Sugar Manufacturing	31	0	31	0
311314	Cane Sugar Manufacturing	53	0	53	4
311340	Nonchocolate Confectionery Manufacturing	514	292	222	363
311351	Chocolate and Confectionery Manufacturing from Cacao Beans	201	107	94	136
311352	Confectionery Manufacturing from Purchased Chocolate	1,148	715	433	931
311411	Frozen Fruit, Juice and Vegetable Manufacturing	218	32	186	43
311412	Frozen Specialty Food Manufacturing	489	118	371	176
311421	Fruit and Vegetable Canning3	842	330	512	427
311422	Specialty Canning	126	44	82	56
311423	Dried and Dehydrated Food Manufacturing	231	37	194	61
311511	Fluid Milk Manufacturing	461	49	412	88
311512	Creamery Butter Manufacturing	52	11	41	16
311513	Cheese Manufacturing	561	99	462	149
311514	Dry, Condensed, and Evaporated Dairy Product Manufacturing	187	21	166	28
311520	Ice Cream and Frozen Dessert Manufacturing	427	180	247	258
311612	Meat Processed from Carcasses	1,358	402	956	608
311615	Poultry Processing	532	85	447	120
311710	Seafood Product Preparation and Packaging	551	146	405	214
311811	Retail Bakeries	6,915	4,558	2,357	6,462
311812	Commercial Bakeries	3,031	1,584	1,447	2,101
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing	220	64	156	85
311821	Cookie and Cracker Manufacturing	380	179	201	231
311824	Dry Pasta, Dough, and Flour Mixes Manufacturing from Purchased Flour	424	120	304	178

311830	Tortilla Manufacturing	384	195	189	248
311911	Roasted Nuts and Peanut Butter Manufacturing	262	51	211	67
311919	Other Snack Food Manufacturing	414	123	291	178
311920	Coffee and Tea Manufacturing	722	347	375	492
311930	Flavoring Syrup and Concentrate Manufacturing	153	35	118	47
311941	Mayonnaise, Dressing and Other Prepared Sauce Manufacturing	368	127	241	165
311942	Spice and Extract Manufacturing	416	87	329	167
311991	Perishable Prepared Food Manufacturing	811	215	596	446
311999	All Other Miscellaneous Food Manufacturing	711	187	524	396
312111	Soft Drink Manufacturing	545	87	458	129
312112	Bottled Water Manufacturing	297	95	202	138
312113	Ice Manufacturing	398	121	277	225
312120	Breweries	3,305	1,873	1,432	2,538
312130	Wineries	3,708	2,326	1,382	2,967
312140	Distilleries	783	440	343	565
325411	Medicinal and Botanical Manufacturing	492	137	355	231
325412	Pharmaceutical Preparation Manufacturing	1,280	279	1,001	410
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	1,230	250	980	567
115114	Postharvest Crop Activities (except Cotton Ginning)	1,088	808	280	475
TOTAL		**37,215**	**17,243**	**19,972**	**23,350**

Each of the 13,865 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 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 141,233 establishments reported in the SUSB in 2017. The average burden to these establishments is 2.3 hours, resulting in a total burden to retailers of 324,835.9 hours. **Table 2** below lists all retailers that have been considered for this information collection and includes fresh fruit and vegetable grocers, wholesalers, and supplement and vitamin stores.

Table 2: List of NAICS codes, code meaning, and number of establishments considered for this information collection for food retailers.

2012 NAICS code	Meaning of 2012 NAICS code	Number of Establishments		
		Total	Small	Large
424410	General Line Grocery Merchant Wholesalers	2636	149	2487
424420	Packaged Frozen Food Merchant Wholesalers	3370	129	3241
424450	Confectionery Merchant Wholesalers	2696	216	2480
424480	Fresh Fruit and Vegetable Merchant Wholesalers	4858	163	4695
424490	Other Grocery and Related Products Merchant Wholesalers	15142	1101	14041
445110	Supermarkets and Other Grocery (except Convenience) Stores	64938	41792	23146
445120	Convenience Stores	28430	26737	1693
445230	Fruit and Vegetable Markets	2736	2575	161
445291	Baked Goods Stores	2876	2372	504
445292	Confectionery and Nut Stores	3451	2412	1039
446191	Food (Health) Supplement Stores	10100	5445	4655
	TOTAL	**141233**	**83091**	**58142**

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 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.**

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 to be$54,590 for all subsequent years, assuming higher overhead costs. A breakdown of the oversight costs for the first year is the following:

Salaries/benefits/awards	$25,750
Travel	$5,150
Printing/Copying/Mailing/ Postage	$1,442
Federal Register Services	$2,472
OGC (legal services)	$16,480
Supplies/equipment	$3,296
TOTAL	$54,590

We do not predict any change to the previously estimated annual federal burden in this information collection.

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

This information collection contains two program adjustments from previous information collection.

Firstly, this collection will not consider any new start-up costs when calculating total burden hours. The previous information collection calculations assumed a one time start-up cost for regulated entities that reflected the cost to reformulate any products or develop labels for products containing bioengineered ingredients. These one time start-up costs have been assumed to be incurred in before the mandatory compliance date of January 1, 2022 and no additional startup costs will be incurred until such time that changes to the AMS List of Bioengineered Foods (the List) are made. Because there have been no changes made to the List since the last collection, we have assumed that no additional startup costs will be incurred.

Secondly, this collection estimates a higher number of retailers that will be impacted than past collections because new regulated entities have been added to the calculation. In 2018 the collection considered only fresh fruit and vegetable grocers. Here we have included food retailers and wholesalers, bakers and dietary supplement retailers. These additions were added based on stakeholder feedback from inquiries into the Standard inbox and requests for presentations on the Standard. Table 3 below lists the regulated entities and their associated NAICS codes used in the previous collection as compared to this collection. Even though the number of impacted retailers increased, the overall estimated burden for this collection is lower than estimated in 2018.

Table 3: List of retailers considered for this collection and their associated NAICS codes

2018 Regulated Entities	
445110	Supermarkets and other grocery (except convenience) stores
424480	Fresh Fruit and Vegetable Merchant Wholesalers

2022 Regulated Entities	
424410	General Line Grocery Merchant Wholesalers
424420	Packaged Frozen Food Merchant Wholesalers
424450	Confectionery Merchant Wholesalers
424480	Fresh Fruit and Vegetable Merchant Wholesalers
424490	Other Grocery and Related Products Merchant Wholesalers
445110	Supermarkets and Other Grocery (except Convenience) Stores
445120	Convenience Stores
445230	Fruit and Vegetable Markets
445291	Baked Goods Stores
445292	Confectionery and Nut Stores
446191	Food (Health) Supplement Stores

Finally, during the 60-day notice period the BLS Wage Rates were updated. The submission has been updated to reflect the most up-to-date wage information.

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.