Recordkeeping Requirements for Gluten-Free Labeling
of Fermented or Hydrolyzed Foods
OMB Control No. 0910-NEW
RIN 0910-AH00
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Information Collection Necessary

Celiac disease, a hereditary, chronic inflammatory disorder of the small intestine, has no cure, but individuals who have this disease are advised to avoid all sources of gluten in their diet to protect against adverse health effects associated with the disease. In the Federal Register of August 5, 2013 (78 FR 47154), the Food and Drug Administration (FDA, we, or us) published a final rule defining the term “gluten-free” and establishing requirements for the voluntary use of that term in food labeling. The final rule, now codified at 21 CFR §101.91, is intended to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with foods so labeled. The regulation provides that "[w]hen compliance with [the rule] is based on an analysis of the food, the FDA will use a scientifically valid method that can reliably detect the presence of 20 parts per million (ppm) gluten in a variety of food matrices, including both raw and cooked or baked products" (§ 101.91(c)). We established this 20 ppm limit for intact gluten considering multiple factors, including currently available analytical methods and the needs of individuals with celiac disease, as well as factors such as ease of compliance and enforcement, stakeholder concerns, economics, trade issues, and legal authorities. Although test methods for the detection of gluten fragments in fermented and hydrolyzed foods have advanced, there is still uncertainty in interpreting the results of these test methods on a quantitative basis that equates the test results to an equivalent amount of intact gluten. Thus, alternative means are necessary to verify compliance with the provisions of the rule for fermented and hydrolyzed foods, such as cheese, yogurt, vinegar, sauerkraut, pickles, green olives, beers, and wine, or hydrolyzed plant proteins used to improve flavor or texture in processed foods such as soups, sauces, and seasonings.

Consistent with section 206 of the Food Allergen Labeling and Consumer Protection Act (FALCPA) and sections 403(a)(1), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(a)(1), 321(n), and 371(a)), we are proposing requirements to permit the voluntary use of the term "gluten free" in the labeling of foods that are fermented, hydrolyzed, or distilled, or that contain fermented, hydrolyzed, or distilled ingredients. While the regulations at 21 CFR 101.91 define the term “gluten-free” and set forth requirements for the voluntary use of the term in food labeling, they do not require manufacturers who label their foods as "gluten-free" to test those foods for its presence. The rulemaking would amend our regulations to provide alternative means for us to verify compliance based on records that are maintained by the manufacturer of the food bearing the "gluten-free" claim and made available to us for inspection and copying.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

Specifically, the proposed rulemaking would amend 21 CFR §101.91 to require that manufacturers of fermented or hydrolyzed foods bearing the "gluten-free" claim create and maintain records regarding the food demonstrating adequate assurances that the food is "gluten-free" before fermentation or hydrolysis and that gluten has not been introduced during the manufacturing process. Likewise, for foods containing one or more fermented or hydrolyzed ingredient and bearing the "gluten-free" claim, manufacturers would be required to create and maintain records demonstrating adequate assurance that the fermented or hydrolyzed ingredients are "gluten-free" under the regulations. Such adequate assurance can include test results, certificates of analysis (CoAs), or other appropriate verification documentation for each of the ingredients used in the food. Alternatively, adequate assurance can include test results of the food before fermentation or hydrolysis of the food. Finally, the rulemaking would require manufacturers to document that any potential for gluten cross-contact has been adequately assessed, and where such a potential has been identified, that measures have been implemented to prevent the introduction of gluten into the food during the manufacturing process.

We believe these information collection requirements will help ensure that the subject foods are adequately labeled and that consumers may rely on the product labeling.

3. Use of Information Technology and Burden Reduction

While the proposed rulemaking does not require the use of specific information technology, we believe that respondents will utilize electronic means to create and maintain the proposed recordkeeping. The records required would need to be reasonably accessible by FDA during an inspection at each manufacturing facility to determine whether the food has been manufactured and labeled in compliance with the regulations. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Business or Other Small Entities

The rulemaking would cover all food products asserting a claim of "gluten free" in the product's label. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

We believe the recordkeeping requirements impose the minimal burden necessary to provide an adequate assurance to consumers that the subject foods are consistent with the product's labeling.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(B)), we solicited public comment on the information collection provisions in our proposed rule of November 18, 2015 (80 FR 71990). Because of an inadvertent error that resulted in conflicting dates by which comments would be received, we extended the comment period to April 25, 2016 (see 81 FR 8869).

9. Explanation of Any Payment or Gifts to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

Records that may be reviewed during FDA inspections are subject to FDA regulations in 21 CFR Part 20. Confidential commercial information is protected from disclosure under FOIA in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Respondents to the information collection are manufacturers of foods that are fermented, hydrolyzed, or contain fermented or hydrolyzed ingredients and bear the claim "gluten-free," "no gluten," "free of gluten," or "without gluten."

Manufacturers using an ingredient that is a hydrolyzed or fermented food only would be required to make and keep these records for the hydrolyzed or fermented ingredient. We estimate that the manufacturers would satisfy the recordkeeping requirements of the proposed rule, if finalized, by maintaining records of their tests or other appropriate verification procedures, their evaluation of the potential for gluten cross contact, and their standard operating procedures (SOPs) for preventing gluten cross-contact. It is also possible that manufacturers would instead comply with this proposed rule by obtaining and maintaining records of Certificates of Analysis, test results, or other appropriate verification procedures from their suppliers. Written SOPs and records of testing and other activities are essential for FDA to be able to determine compliance with §101.91 (the gluten-free regulation) for these products.

We estimate the burden of this collection of information below. Our estimates of the average burden per recordkeeping on our experience with good manufacturing practice used to control the identity and composition of food and to limit contaminants and prevent adulteration. The hour estimates for the recordkeeping burdens presented are averages. We anticipate that the records kept would vary based on the type of ingredients used. Some manufacturers, such as those producing fermented dairy products, would likely maintain fewer records overall. Other manufacturers, such as those producing foods with fermented or hydrolyzed grains, legumes, or seeds, would likely maintain more extensive records.

The estimated number of respondents (recordkeepers) reported in column 2 of tables 1 and 2 is based on the number of food products covered by the rulemaking. We searched the FoodEssentials database for foods that are hydrolyzed, fermented, or contain fermented or hydrolyzed ingredients and bear the claim "gluten-free," "no gluten," "free of gluten," or "without gluten," and found approximately 2,500 products that would be subject to the rulemaking. We estimate that this database has at least half of all products that would be covered by the proposed rule, so that there would be, at most, 5,000 products affected by the proposed rule. We have no data on products produced in each facility, so we assume that each product and its production line would be tested separately and would require a separate evaluation and SOP. Thus, we estimate the number of food production facilities and, accordingly, the number of manufacturers/recordkeepers to be 5,000. If multiple products are produced in the same facility and can share testing, evaluation, and SOPs, then the recordkeeping burden would be less than these estimates.

We do not know how many of these products are already being manufactured using gluten-free ingredients and/or with a process designed to prevent gluten introduction. A survey of food industry practices shows that about 45 percent of all food production facilities have a written allergen control plan, and about 39 percent require certificates of analysis for ingredients. Given that producers of foods labeled “gluten-free” are marketing to customers who care more about gluten cross-contact, we estimate that about 75 percent of the 5,000 foods with a “gluten-free” labeling claim already have a written plan for preventing the introduction of gluten into the food product that includes the testing of ingredients and also procedures for evaluating and preventing gluten cross-contact. Therefore, we estimate that 1,250 facilities would incur new SOP development and ingredient testing burdens and all 5,000 facilities would incur certain new recordkeeping burdens.

Recordkeeping Burden Related to Standard Operating Procedures

We estimate that 1,250 facilities do not have a written SOP for preventing the introduction of gluten into the food product. For these facilities, developing an SOP would be a one-time burden. We estimate that it would take a facility an average of 7 hours to develop an SOP for gluten control. Thus, we estimate that in the first year of compliance with the proposed rule if finalized, 1,250 facilities would develop an SOP for a burden of 8,750 hours (1,250 x 7 = 8,750), as reported in table 1, row 1.

Updating the facility's SOP for gluten control would be a recurring burden of the proposed rule for the 1,250 facilities that do not currently have an SOP. We estimate that it would take a facility about 0.7 hours (42 minutes) annually to update its SOP for gluten control, for a burden of 875 hours (1,250 x 0.7 = 875), as reported in table 2, row 1.

We estimate that maintaining records of their updated SOPs would be a recurring burden of the proposed rule for all 5,000 facilities. We estimate that it would take each facility 1 hour annually to maintain records of its updated SOPs for gluten control, for a burden of 5,000 hours (5,000 x 1 = 5,000), as reported in table 2, row 2.

Recordkeeping Burden Related to Testing

In order to demonstrate that the food is gluten-free before fermentation or hydrolysis, we expect that most manufacturers would test incoming ingredients or obtain Certificates of Analysis from ingredient suppliers. A manufacturer may test its ingredients for gluten by sending ingredient samples to a testing company or by using test kits to test ingredient samples on site at its facility. Test kits would first undergo method validation for the testing situation in which they are to be used. We assume that a manufacturer that begins a program of testing the gluten content of an ingredient will start by sending several samples to a lab and obtaining method extension for a test kit for the ingredient. Obtaining a validation for a test kit is a one-time burden.

After the first year of testing, we assume manufacturers would then use test kits to test the ingredient on a regular basis, and may also send one or two samples a year to an outside lab for testing. These are recurring recordkeeping burdens. We estimate that an average of two ingredients per product would be tested in this manner. Most foods affected by the rulemaking are those that contain a single hydrolyzed or fermented ingredient, so any testing would have been done by the ingredient supplier before that supplier performed hydrolysis or fermentation. Other products contain several ingredients that would be tested before fermentation or hydrolysis.

In the first year of compliance, we estimate that the 1,250 manufacturers not currently testing ingredients and production facilities for gluten would incur additional testing burdens as a result of the rulemaking. For these manufacturers, obtaining a method extension for a test kit would be a one-time burden. We estimate that 1,250 manufacturers would conduct seven tests for method extension, for each of two ingredients, for a total of 14 samples. We estimate that it would take a manufacturer 5 minutes to collect each sample, for a total of 1,453 hours (1,250 x 14 x (5 ÷ 60) = 1,453) as reported in table 1, row 2. We estimate that this proposed rule would result in manufacturers conducting 17,500 laboratory tests in the first year (1,250 x 14 = 17,500). These tests have an average cost of $84.33, so we calculate capital costs related to this one-time recordkeeping to be $1.5 million (17,500 x $84.33 = $1,475,833) as reported in table 1, row 2.

We estimate that, as a one-time burden, all 5,000 manufacturers would begin retaining records of the method extension tests. We estimate it would take a manufacturer 30 minutes per record, for a total of 35,000 hours (5,000 x 14 × 0.5 = 35,000), as reported in table 1, row 3.

We estimate a recurring recordkeeping burden for regular testing of ingredients for approximately 1,250 manufacturers not currently testing ingredients and production facilities for gluten. We estimate these 1,250 manufacturers will use 21 test kits annually on average per ingredient, for a total of 42 kits, and that each test will require 5 minutes to collect a sample and 30 minutes to process and record test results. We estimate that the burden of collecting samples for these tests would be 4,358 hours (1,250 x 21 x (5 ÷ 60) = 4,358), as reported in table 2, row 3. We estimate this results in manufacturers using 52,500 test kits each year (1,250 x 42 =

52,500). These test kits have an average cost of $11, which means that the estimated capital costs related to this recordkeeping is $0.6 million (52,500 x $11 = $577,500), as reported in table 2, row 3. We estimate the burden to process and maintain records of the test results would be 105,000 hours (5,000 x 42 x 0.5 = 105,000), as reported in table 2, row 4.

We estimate that a recurring burden of the proposed rule, if finalized, for all 5,000 manufacturers would be to send one or two samples a year to an outside lab for testing. We estimate that 5,000 manufacturers will conduct one outside test annually on average per ingredient, for a total of 2 tests, and that each test will require 5 minutes to collect a sample and 30 minutes to process and file the test results. We estimate that the burden of collecting samples for these tests would be 208 hours (1,250 x 2 x (5 ÷ 60) = 208), as reported in table 2, row 5. We estimate that this proposed rule would result in manufacturers conducting 2,500 laboratory tests in the first year (1,250 x 2 = 2,500). These tests have an average cost of $84.33, which means that the estimated capital costs related to this recurring paperwork burden is about $0.2 million (2,500 x $84.33 = $210,833), as reported in table 3, row 5. We estimate the burden to process and maintain records of the test results would be 5,000 hours (5,000 x 2 x 0.5 = 5,000), as reported in table 2, row 6.

Table 1 – Estimated One-Time Recordkeeping Burden

Activity under 21 CFR 101.91	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours	Capital Costs[1]
Developing SOP for gluten control	1,250	1	1,250	7	8,750	0
Collecting samples for testing	1,250	14	17,500	0.083	1,453	$1.5
Maintaining records of method extension tests	5,000	14	70,000	0.5	35,000	0
TOTAL			88,750		45,203	$1.5

[1] US Dollar Millions

Table 2 – Estimated Annual Recordkeeping Burden

Activity under 21 CFR 101.91	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours	Capital Costs[1]
Updating SOP for gluten control	1,250	1	1,250	0.7	875	0
Maintaining records of updated SOP for gluten control	5,000	1	5,000	1	5,000	0
Collecting samples for test kit testing	1,250	42	52,500	0.083	4,358	$0.6
Maintaining records of test kit test results	5,000	42	210,000	0.5	105,000	0

Activity under 21 CFR 101.91	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours	Capital Costs[1]
Collecting samples for testing by outside lab	1,250	2	2,500	0.083	208	$0.2
Maintaining records of testing by outside lab	5,000	2	10,000	0.5	5,000	0
TOTAL			281,250		120,441	$0.8

[1] US Dollar Millions

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers

We estimate no other cost burden to respondents.

14. Annualized Cost to the Federal Government

15. Explanation of Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.