VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this proposed rule.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on November 10, 2015.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, DOE is proposing to amend parts 429 and 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 2. Section 429.37 is amended by adding paragraphs (b)(3) and (c) to read as follows:

§ 429.37 External power supplies.

* * * * *

(b) * * *

(3) Pursuant to § 429.12(b)(13), a certification report for external power supplies that are exempt from the energy conservation standards at § 430.32(w)(1)(ii) pursuant to § 430.32(w)(2) must include the following additional product-specific information: The number of units of each individual model of exempt external power supplies sold during the most recent 12-calendar-month period ending on July 31.

(c) *Exempt External Power Supplies.* For each individual model of external power supply that is exempt from energy conservation standards pursuant to § 430.32(w)(2) and has not been certified pursuant to § 429.12(a) as compliant with an applicable standard, the importer or domestic manufacturer must, no later than September 1, 2017, and annually thereafter, submit a report providing the following information:

(1) The importer or domestic manufacturer's name and address;

(2) The brand name;

(3) The model number;

(4) The average active mode efficiency as a percentage (%);

(5) No-load mode power consumption in watts (W);

(6) The nameplate output power in watts (W);

(7) The nameplate output current in aperes (A); and

(8) The number of units sold during the most recent 12-calendar-month period ending on July 31. The report must be submitted to DOE in accordance with the submission procedures set forth in § 429.12(h).

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 3. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 4. Section 430.32 is amended by revising paragraph (w)(2) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(w) * * *

(2) A basic model of external power supply is not subject to the energy conservation standards of paragraph (w)(1)(ii) of this section if the external power supply—

(i) Is manufactured during the period beginning on February 10, 2016, and ending on February 10, 2020;

(ii) Is marked in accordance with the External Power Supply International Efficiency Marking Protocol, as in effect on February 10, 2016;

(iii) Meets, where applicable, the standards under paragraph (w)(1)(i) of this section, and has been certified to the Secretary as meeting those standards; and

(iv) Is made available by the manufacturer only as a service part or a spare part for an end-use product that—

(A) Constitutes the primary load; and

(B) Was manufactured before February 10, 2016.

* * * * *

[FR Doc. 2015–29303 Filed 11–17–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2014–N–1021]

RIN 0910–AH00

Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to establish requirements concerning ''gluten-free'' labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These additional requirements for the ''gluten-free'' labeling rule are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to fermented or hydrolyzed foods labeled as ''gluten-free.'' There is uncertainty in interpreting the results of current gluten test methods for fermented and hydrolyzed foods on a quantitative basis that equates the test results in terms of intact gluten. Thus, we propose to evaluate compliance of such fermented and hydrolyzed foods that bear a ''gluten-free'' claim with the gluten-free labeling rule based on records that are made and kept by the manufacturer of the food bearing the ''gluten-free'' claim and made available to us for inspection and copying. The records would need to provide adequate assurance that the food is ''gluten-free'' in compliance with the gluten-free food labeling final rule before fermentation or hydrolysis. In addition, the proposed rule would require the manufacturer of fermented or hydrolyzed foods bearing the ''gluten-free'' claim to document that it has adequately evaluated the potential for gluten cross-contact and, if identified, that the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process. Likewise, manufacturers of foods that contain fermented or hydrolyzed ingredients and bear the ''gluten-free'' claim would be required to make and keep records that demonstrate with adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free'' in compliance with the gluten-free food labeling final rule. Finally, the proposed rule would state that we would evaluate compliance of distilled foods by

verifying the absence of protein using scientifically valid analytical methods that can reliably detect the presence of protein or protein fragments in the distilled food.

DATES: Submit either electronic or written comments on the proposed rule by February 16, 2016. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 18, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–N–1021 for Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods.

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Carol D'Lima, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371, FAX: 301–436–2636.

With regard to the information collection issues: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Rule

Need for the rule: 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), we published a final rule that defines the term ''gluten-free'' and establishes requirements for the voluntary use of that term in food labeling. The final rule (now codified at § 101.91 (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 respect to 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.

Legal authority: 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.

Major provisions of the rule: The proposed rule would amend § 101.91(c) 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. We propose that, for foods fermented or hydrolyzed by the manufacturer and bearing the ''gluten-free'' claim, the records must demonstrate adequate assurance that the food is ''gluten-free'' in compliance with § 101.91(a)(3) before fermentation or hydrolysis. 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.

In addition, the proposed rule would require the manufacturer to document that any potential for gluten cross-contact has been adequately assessed, and where such a potential has been identified, that the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.

Further, for foods containing one or more fermented or hydrolyzed ingredients and bearing the ''gluten-free'' claim, manufacturers would have to make and keep records demonstrating with adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free'' in compliance with § 101.91(a)(3) including, but not limited to, CoAs or other appropriate verification documentation from the ingredient suppliers and/or results of testing conducted by the ingredient suppliers.

The proposed rule also would require the manufacturer to retain the records for at least 2 years after introduction or delivery for introduction of the food into interstate commerce. The proposed rule would allow these records to be kept as original records, as true copies or as electronic records, and manufacturers would have to make the records available to us for inspection and copying, upon request, during an inspection. The records would need to be reasonably accessible to FDA during an inspection at each manufacturing facility (even if not stored on site) to determine whether the food has been manufactured and labeled in compliance with § 101.91. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible. The proposed rule would provide that we would evaluate compliance of distilled foods, such as distilled vinegar, by verifying the absence of protein using scientifically valid analytical methods that can reliably detect the presence of protein or protein fragments in the food.

Costs and benefits: Full compliance with the proposed rule, if finalized, would have annualized costs of about $9 million per year and annual health benefits of about $41 million per year, for net benefits of $32 million a year:

ANNUAL COST AND BENEFIT OVERVIEW

Costs	Testing of Foods	$3,000,000
	Standard Operating Procedure Development	1,500,000
	Labeling (changes for non-compliant products)	300,000
	Paperwork	3,900,000
Benefits	Health Gains for Individuals with Celiac Disease	41,000,000
Net Benefits		32,000,000

Table of Contents

I. Background

A. Why do we need this proposed rule?

Celiac disease is a hereditary, chronic inflammatory disorder of the small intestine triggered by the ingestion of certain proteins referred to as gluten occurring in wheat, rye, barley, and crossbreeds of these grains. The main protein of wheat gluten is gliadin; the similar proteins of rye and barley are termed secalin and hordein, respectively. Both of the major protein fractions of gluten, gliadins and glutenins, are active in celiac disease. All the gliadins and glutenins subunits are reported to be harmful for individuals with celiac disease (Ref. 1). Celiac disease has no cure, and 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.

Under section 206 of FALCPA, in the **Federal Register** of August 5, 2013, we published a final rule that defines the term ''gluten-free'' and establishes requirements as to the voluntary use of that term in food labeling. The final rule (now codified at 21 CFR 101.91) is intended to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to foods labeled as ''gluten-free.'' The final rule does not require manufacturers who label their foods as ''gluten-free'' to test those foods for the presence of gluten

although they may choose to do so to ensure that the food does not contain 20 ppm or more gluten. The regulation provides that ''[w]hen compliance with [the rule] is based on an analysis of the food, FDA will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices, including both raw and cooked or baked products'' (§ 101.91(c)). We may conduct such testing to verify that foods labeled ''gluten free'' meet the criteria for ''gluten-free'' labeling, including the part of the ''gluten-free'' definition that states that ''[a]ny unavoidable presence of gluten in the food bearing the claim in its labeling is below 20 ppm gluten (*i.e.,* below 20 mg gluten per kg of food)'' (§ 101.91(a)(3)(ii)).

In comments we received in response to the proposed rule that appeared in the **Federal Register** of January 23, 2007 (72 FR 2795), and to a related notice we published in the **Federal Register** of August 3, 2011 (76 FR 46671), we became aware that fermented or hydrolyzed foods, some of which are labeled as ''gluten-free,'' cannot be tested for a quantitative measure of intact gluten using currently available analytical methods. In the notice that we published in the **Federal Register** of August 3, 2011 (76 FR 46671 at 46673), we stated that FDA recognized that for some food matrices (*e.g.,* fermented or hydrolyzed foods) there were no currently available validated methods that could be used to accurately determine if they contained <20 ppm gluten. FDA also stated that we were considering whether to require manufacturers of such foods to have a scientifically valid method that would reliably and consistently detect gluten at 20 ppm or less before including a ''gluten-free'' claim in the labeling of their foods. FDA requested comments on this proposed approach as well as on whether FDA also should require these manufacturers to maintain records on test methods, protocols, and results and to make these records available to FDA upon inspection.

The notice explained that we interpret the term ''scientifically valid method'' to mean a method that is ''accurate, precise, and specific for its intended purpose and where the results of the method evaluation are published in the peer-reviewed scientific literature. In other words, a scientifically valid test is one that consistently and reliably does what it is intended to do'' (id.).

As of November 18, 2015, we know of no scientifically valid analytical method effective in detecting and quantifying with precision the gluten protein content in fermented and hydrolyzed foods in terms of equivalent amounts of intact gluten proteins. Without reference standards associated with the production of fermented and hydrolyzed products, such quantification is uncertain and potentially inaccurate (Ref. 2). Thus, we need other means to verify compliance for these foods.

B. What are fermented or hydrolyzed foods?

A fermented food is one that has undergone fermentation—a process that typically involves the conversion of complex organic compounds, especially sugars and other carbohydrates, to simpler compounds such as lactic acid and ethyl alcohol. Fermentation has long been used to preserve or produce foods with characteristic flavors or textures. During fermentation, proteins such as gluten break apart into smaller groups of amino acids known as peptides. Examples of foods that are subject to fermentation during manufacturing are cheese, yogurt, vinegar, sauerkraut, pickles, green olives, beers, and wine.

A hydrolyzed food is one in which a food's chemical components—such as proteins—are broken into smaller organic compounds by reaction with water. These reactions are often accelerated by enzymes. One common application of hydrolysis in food manufacturing is the hydrolysis of plant proteins—such as soy protein. Hydrolyzed soy proteins are often used as an ingredient to increase digestibility of the protein, to enhance flavor, or to improve texture in processed foods such as soups, sauces, and seasonings. There are many different types of fermented or hydrolyzed foods as well as food products that contain fermented or hydrolyzed ingredients (Ref. 3). Examples of foods that use hydrolyzed plant proteins as flavor enhancers include soups, chili, sauces, gravies, stews, dips, and some snacks like potato chips and pretzels.

C. Why are there no appropriate analytical methods to quantify intact gluten in fermented or hydrolyzed foods?

1. Background on Analytical Methods for Gluten

As discussed in the preamble to our final rule (78 FR 47154 at 47165), we routinely rely upon scientifically valid methods in our enforcement programs on food labeling. When we established the requirement that foods bearing the ''gluten-free'' claim contain less than 20 ppm of intact gluten, we were referring to intact gluten as measured by sandwich ELISA-based methods. (ELISA stands for an enzyme-linked immunosorbent assay.) The sandwich ELISA-based methods can both detect and quantify specific amino acid sequences, known as epitopes, with the requirement that at least two epitopes be present in a single strand of amino acids in order to mediate the binding of two antibodies (hence, the concept of a sandwich). Advantages of sandwich ELISA-based methods are an increased specificity associated with the requirement that two antibodies bind the antigen (especially if the two antibodies recognize different epitopes) and a high sensitivity. As a result, the sample does not have to be extensively purified before analysis (Ref. 4).

Sandwich ELISA-based methods are appropriate for foods in which the gluten is not subject to fermentation or hydrolysis and remains intact. However, as we discuss in the next section, sandwich ELISA-based methods are not effective in detecting and quantifying gluten proteins that are no longer intact as a result of fermentation or hydrolysis.

2. Challenges in Quantifying Gluten in Fermented and Hydrolyzed Foods

Proteins can be broken into smaller fragments called peptides. Unless the proteins are sufficiently broken down so as to eliminate all immunopathogenic elements (*e.g.,* strands of amino acids that cause a celiac response), the fermented or hydrolyzed gluten can be harmful to people with celiac disease (Ref. 5). Compared to other processing methods that physically remove the gluten to produce non-protein containing ingredients (*e.g.,* wheat starch), fermentation, hydrolysis, or enzymatic processing methods that chemically break down gluten peptides may not completely remove the immunotoxic potential of these peptides. Small gluten peptides resulting from these processes and remaining in the finished food could still contain sequences of amino acids which potentially cause adverse reactions in people with celiac disease. We invite comments, including scientific data, on any studies that have been conducted to demonstrate whether any fermentation or hydrolytic processes sufficiently break down gluten into peptides that are harmless to persons with celiac disease.

The principal limitation of the sandwich ELISA-based methods is that they need at least two epitopes recognized by the antibodies used in the assay to be present in the same continuous amino acid strand. However, in fermented or hydrolyzed foods, gluten proteins are typically fragmented

into peptides. Although these peptides may remain immunologically active and be of potential concern to people with celiac disease, the antibodies used in the ELISA-based methods may be unable to recognize the peptides. This affects how one might detect and quantify gluten, such that the quantity of gluten reported may be incorrect (Ref. 6). Thus, sandwich ELISA-based methods are not appropriate analytical methods for detecting and quantifying gluten content in fermented or hydrolyzed products.

Competitive ELISA-based methods that recognize a single epitope have been developed and may overcome the detection problems encountered with the sandwich ELISA-based assays in hydrolyzed or fermented food. Although some studies have validated the reproducibility of competitive ELISA-based test methods (Ref. 7), there is uncertainty about whether these methods can quantify the amount of protein from which those fragments were generated by hydrolysis (Ref. 2). This uncertainty creates problems in equating these test results to an equivalent amount of intact gluten in the fermented or hydrolyzed product. Further, without an appropriate reference standard to gauge the response, one cannot interpret the results on a quantitative basis that equates the response to a specific amount of intact gluten. As of November 18, 2015, we are not aware of any methods for which there is an appropriate reference standard to gauge the response for detection and quantification, with precision, of the gluten content in terms of intact gluten in fermented and hydrolyzed foods.

In addition to ELISA-based methods, mass spectrometry (MS) holds significant potential for analysis of hydrolyzed gluten because of its unique capabilities for protein and peptide analysis. In general, MS can provide accurate measurement of peptide molecular weights and identification of peptide primary amino acid sequences. Qualitative methods can be used to determine the identity of the peptides, with quantitative methods able to determine peptide concentrations. As applied to hydrolyzed gluten analysis, MS analysis may be able to identify and quantify the gluten protein fragment peptides that result from food processing. Therefore, for hydrolyzed food, MS could identify gluten and measure gluten fragment concentrations with high sensitivity and molecular specificity. However, without an appropriate hydrolyzed gluten reference standard that would enable interpretation of the test results in terms of intact gluten, as well as the ability to analyze for all potential peptides, MS analysis would not be able to provide a quantitative measure of intact gluten. Therefore, methods are needed that can not only detect gluten protein hydrolysis fragments, but also quantify the source gluten proteins. We invite comment on any additional research into methods that can be used to quantify the gluten protein content in fermented or hydrolyzed foods in terms of intact gluten, including the use of ELISA-based methods and MS testing, as well as any data and information on appropriate reference standards for such test methods.

D. Is it feasible, and under what circumstances, can foods be processed to remove gluten?

In some cases, it is possible to remove or separate the gluten protein portion of an ingredient derived from a gluten-containing grain. For example, in processing food starch from various grain sources including wheat, the starch is extracted and refined from the grains by wet grinding, washing, and sieving to separate the protein components from the starch. This starch material can be dried or used in further processing. However, some gluten may remain in these ingredients even after they have been processed to remove gluten. Variations in the processing could result in different trace amounts of gluten remaining in the starch. Therefore, § 101.91(a)(3)(i)(A)(*3*) provides that the use of such ingredients must not result in the presence of 20 ppm or more gluten in the finished food (*i.e.,* 20 mg or more gluten per kg of food).

Our regulations do not allow for processing a food (as opposed to the food's ingredients) to remove gluten. Section 101.91(a)(3)(i)(A)(*1*) requires that the food bearing the claim in its labeling not contain an ingredient that is a gluten-containing grain (*e.g.,* spelt wheat). The intent behind § 101.91(a)(3)(i)(A)(*1*) was to ensure that the food, as consumed, contains as little gluten as possible. This approach is consistent with other international standards (see Codex Standard 118–1979, section 2.1.1 (Ref. 8)).

Nevertheless, we have heard arguments that we should allow the use of a ''gluten-free'' label on foods where the food, rather than the food's ingredients, has been processed to remove gluten. We have not received sufficient information regarding any specific processes to remove gluten to determine whether any processes identified would impact our rationale. Thus, we invite comment and data on the feasibility and circumstances under which a food can be processed to remove gluten and the methods by which the absence of gluten can be determined.

E. Can beer be labeled ''gluten-free''?

Some comments submitted in response to the 2007 proposed rule and the 2011 notice wanted us to allow beers subject to FDA labeling regulations to be labeled ''gluten-free'' if the beers contained less than 20 ppm gluten, regardless of whether the beer was made from a gluten-containing grain. Other comments favored prohibiting the use of a ''gluten-free'' claim on the label of beers made from gluten-containing ingredients but whose manufacturers claim were later ''reduced'' in gluten by the processing methods.

The comments favoring the use of ''gluten-free'' labeling on beers made from gluten-containing grains argued that the beers can be processed to remove gluten. As with other foods, beers that have been made using a gluten-containing grain do not meet the gluten-free definition. Thus, beers made from gluten-containing grains cannot bear a ''gluten-free'' claim. However, as with other foods, if the gluten-containing grain has been processed to remove gluten in accordance with the provisions in the ''gluten-free'' definition prior to making beer, the beer may be eligible to make the claim under the provisions of this proposed rule. Regarding the commenters' assertion that beers made from gluten containing grains can be processed to remove gluten, we are not aware of any scientifically valid way to evaluate such a claim, and there is inadequate evidence concerning the effectiveness of the commenters' gluten removal process.

Gluten can be at least partially broken down by several processes, including fermentation. However, as we explained in section I.C.1., the presence or absence of gluten broken down in this way cannot be reliably detected with sandwich ELISA-based methods. We are interested in learning more about the efficacy of competitive ELISA-based methods (*e.g.,* the R5 or G12 competitive ELISA-based methods), given the beer industry's practice of adding enzymes to the beer to prevent the problem of cloudiness or ''haze,'' which can occur as a result of residual protein substances extracted from grain during the brewing and fermentation process. The enzyme hydrolyzes or breaks down gluten proteins at proline residues. As a result, adding these haze control enzymes may generate peptides that are not detectable

using the commercially available competitive ELISA-based methods that rely on the presence of proline in the epitopes (Refs. 9 and 10). However, it is uncertain that cleavage at proline residues totally eliminates the concern for people with celiac disease because there may be immunopathogenic protein fragments still present.

FDA recently completed a study on the effectiveness of proline endopeptidase (PEP), an enzyme that the beer industry uses to remove cloudiness in beer, using sorghum beer spiked with gluten as a model system. The study examined the hydrolysis of gluten and some of the protein fragments reported to affect people with celiac disease. The results indicated that fermentation of beer resulted in a gradual reduction in detectable gluten concentration, and addition of PEP increased the reduction in the detectable gluten concentration. However, differences in peptide profiles between the beer and the calibration standards may lead to inaccurate quantitation of gluten in the final product (Ref. 11). Due to the lack of clinical data and a comprehensive understanding of celiac disease, it is not known if immunopathogenic compounds remain after the use of the enzyme. Hydrolyzed gluten may contain protein fragments that can trigger reactions in people with celiac disease which are not recognized by the ELISA methods used or identified by the MS analysis. For example, Western Blot testing showed that high molecular weight glutenins were less susceptible than the low molecular weight fraction of gluten to the action of PEP during the fermentation of beer. Additional data on the effect of PEP, and possibly clinical evidence, are needed before conclusions can be drawn regarding the effectiveness of PEP in breaking down gluten in a manner that renders the beer, or other foods containing gluten, safe for consumption by people with celiac disease.

We are interested in receiving comment, including scientific research regarding whether beer derived from gluten-containing grains that may still contain protein fragments from gluten can be shown by scientifically valid analytic methods to equate to intact gluten on a quantitative basis. We are also interested in scientific research regarding how we can use such test methods to determine that beer derived from gluten-containing grains contains the equivalent of less than 20 ppm intact gluten proteins, including any data and information regarding quantification of gluten fragments and determining appropriate calibration or reference standards. We also invite comment, including data and any information, on scientific research and methods to determine if a specific enzymatic treatment (or other treatments, if known) of beer derived from gluten-containing grains can modify proteins or protein fragments such that they are present at levels equivalent to less than 20 ppm intact gluten protein.

We note that the labeling of beer is subject to oversight by two separate Federal Agencies. As we explained in the preamble to the final rule (78 FR 47154 at 47165), the Treasury Department's Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for the issuance and enforcement of regulations with respect to the labeling of beers that are malt beverages under the Federal Alcohol Administration Act (FAA Act). Certain other beers do not meet the definition of a malt beverage under the FAA Act (27 U.S.C. 211(a)(7)); those beers are subject to FDA's labeling requirements. We are working with TTB on the issues associated with ''gluten-free'' labeling of beer to promote consistency in our approach, while taking into consideration the differences in the statutes administered by FDA and TTB, respectively.

As we noted in the preamble to the final rule (78 FR 47154 at 47166) beer manufacturers whose beers are subject to FDA's labeling requirements that make beer from a gluten-containing grain or from non-gluten-containing grains are not precluded from using other statements on the label, such as a gluten statement consistent with the TTB Policy on Gluten Content Statements in the Labeling and Advertising of Wine, Distilled Spirits, and Malt Beverages, about processing of beers to reduce gluten. However, such statements must be truthful and not misleading. Beers bearing statements related to the gluten processing or content other than ''gluten free'' are still subject to sections 403(a)(1) and 201(n) of the FD&C Act.

F. Can a distilled food be labeled ''gluten-free''?

The preamble to the final rule (78 FR 47154 at 47174) noted that we had received comments expressing concern that distilled vinegar, as a food product or ingredient, could contain gluten and wanted us to not allow distilled vinegar to be labeled as ''gluten-free.'' We indicated that we would consider the comments received on distilled foods, including distilled vinegar, in this proposed rule.

The process of distillation involves heating a liquid such that components with lower boiling points are vaporized and recovered separate from components with higher boiling points. The remaining compounds, whose boiling points were too high to undergo vaporization, are left behind (Ref. 12). We are aware of two commonly used distilled foods subject to FDA labeling regulations; distilled vinegar and distilled water. Of these, distilled water is inherently gluten-free.

There are several different types of vinegars, and not all of them are distilled, as discussed in the Food and Drug Administration, Compliance Policy Guide Sec. 525.825, ''Vinegar Definitions—Adulteration With Vinegar Eels'' (Ref. 13). Some examples of these include cider vinegar (also known as apple vinegar or simply ''vinegar''), wine vinegar (also known as grape vinegar), malt vinegar, sugar vinegar, and glucose vinegar. All vinegars are made by alcoholic and subsequent acetous fermentation, but can be derived from different substances. Cider vinegar is made from the juice of apples; whereas, wine vinegar is made from the juice of grapes. In addition, some vinegars may be made from gluten-containing grains, such as malt vinegar, which is the product made by the alcoholic and subsequent acetous fermentation, without distillation, of an infusion of barley malt or cereals whose starch has been converted by malt.

Distilled vinegar is commonly made from ethanol derived from corn or sugar cane, but, to a lesser extent, other raw materials can be used to derive the ethanol used to make distilled vinegar. Distilled vinegar (also known as spirit vinegar or grain vinegar) is made by the acetous fermentation of dilute distilled alcohol. The alcohol derived from the initial alcohol fermentation undergoes distillation followed by acetous fermentation. Because distillation is a purification process, separating volatile components like alcohol and flavors from non-volatile materials like proteins and sugars, it is unlikely that gluten (or *any* other protein or protein fragments) is present in distilled vinegar if the distillation process is conducted following good manufacturing practices specific to distillation. Although we are not aware of any analytical methods that can be used to reliably detect and accurately quantify the presence of gluten in distilled vinegar, we are aware of analytical methods that could be used to detect the presence of protein and protein fragments as a means for manufacturers to ensure the absence of protein (and thus gluten). We discuss how the proposed rule addresses these methods in section II.D.

Vinegars that are made from gluten-containing grains but are not further processed by distillation may not bear the gluten-free claim under § 101.91(b). For example, some malt vinegars are the product of fermentation, without distillation, of an infusion of barley malt or cereals whose starch has been converted to malt (Ref. 14). Because these types of malt vinegar are derived from gluten-containing grains that have not been distilled or otherwise processed to remove gluten, they may not be used as ingredients in a food bearing a ''gluten-free'' claim or bear such a claim themselves as provided in § 101.91(a)(3)(i)(A)(*2*). Distilled vinegars that are made from gluten-containing grains are first subjected to an alcohol fermentation process followed by distillation and finally an acetous fermentation process of the distilled, diluted alcohol. Distillation in this case is considered as the ''process to remove gluten'' from the ingredient alcohol, which has been derived from the fermentation of the sugars in the grains, and which is then further fermented to produce vinegar. Distilled vinegars that meet the definition of gluten-free may bear the ''gluten-free'' claim under § 101.91(b). Thus, when a food or ingredient bearing the ''gluten-free'' claim is distilled, we will evaluate compliance by verifying the absence of protein in the food or ingredient using a scientifically valid method that can reliably detect the presence or absence of protein or protein fragments in the food. When choosing a method that will verify the absence of protein, among the factors that need to be considered is the sensitivity of the test method for this purpose, such as a limit of detection as close to zero as possible.

G. How do I evaluate gluten cross-contact?

As we noted in the preamble to the final rule, ''[i]n the context of this rule, [gluten] cross-contact occurs when a food without gluten comes in contact with a gluten-containing food or ingredient, resulting in the presence of gluten in the food not intended to contain gluten'' (78 FR 47154 at 47173). We recognize that the supply chain for raw materials, ingredients, and intermediate products used in the food industry can be complex and involve many suppliers outside the manufacturer's immediate control. Thus, for raw materials, ingredients, and intermediate products, the potential for cross-contact with gluten-containing sources may exist.

For example, official regulatory standards, notably the U.S. Department of Agriculture's Grain Inspection, Packers and Stockyards Administration's (GIPSA's) Federal Grain Inspection Service (FGIS), allow for the adventitious presence of other grains. The FGIS is intended to provide farmers, grain handlers, processors, exporters, and international buyers with information that accurately and consistently describes the quality and quantity of grain being bought and sold (Ref. 15). However, the GIPSA definitions for soybeans, canola, flaxseed, sunflower seeds, corn, and oats, by virtue of their allowance of ''other grains,'' do not prohibit the presence of gluten-containing grains.

The ''other grains'' for which standards exist under the United States Grain Standards Act (Pub. L. 64–90) include barley, rye, triticale, and wheat (see 7 CFR 810.201 (definition of barley), 810.1201 (definition of rye), 810.2001 (definition of triticale), and 810.2201 (definition of wheat)), and these are gluten-containing grains. Therefore, records demonstrating assurance for raw materials such as grains, legumes, and seeds may include certificates of analysis or test results drawn from more frequent sampling or more lots of these source materials.

Conversely, there are certain fermented or hydrolyzed foods, such as those fermented or hydrolyzed from vegetable, meat, and dairy ingredients, that have a low probability of cross contact with gluten-containing grains because the source ingredients for these foods are inherently free of gluten and are less likely to come into contact with gluten-containing grains before being processed. Examples of such foods include cheese, yogurt, some vinegars, sauerkraut, pickles, green olives, meats, and wine. Through the use of manufacturing practices that can prevent gluten cross-contact situations, these fermented or hydrolyzed foods made from source ingredients that are inherently free of gluten may present less potential for the presence of gluten.

Given the variety of fermented or hydrolyzed foods and different manufacturing processes for foods fermented or hydrolyzed by the manufacturer and bearing the ''gluten-free'' claim, we believe that decisions as to how to adequately evaluate any potential for gluten cross-contact during the manufacturing process are best left to manufacturers and their manufacturing operations. Likewise, the manufacturer must determine what measures they should take to prevent the introduction of gluten into the food during the manufacturing process. Manufacturers must keep records adequately evaluating the potential for gluten cross-contact and documenting the measures used to prevent the introduction of gluten into the food during the manufacturing process.

We invite comment on the potential for source ingredients used in fermentation (*i.e.,* milk in yogurt) to come in contact with gluten-containing grains, and on manufacturing practices that can prevent risk of gluten cross contact.

H. Can a fermented or hydrolyzed food be concentrated or dried?

As we explained in the preamble to the final rule (78 FR 47154 at 47159), 20 ppm gluten is a concentration level rather than an absolute quantity of gluten in a food. If a food's ingredients are all below 20 ppm gluten, the food containing those ingredients will have a gluten concentration less than 20 ppm.

When water or other liquid is removed from a food, for example a soup or sauce, or the product is dried, the relative concentration of the material dissolved or suspended in the product increases as the water or dissolving material is removed. In the case of gluten in a product, we are aware that the relative concentration of gluten could increase if water or other liquid is removed. Given the limitations of gluten testing and the variety of processes involved in concentration or drying of fermented or hydrolyzed ingredients, there could be uncertainty in the determination of the amount of gluten contained in these materials. For this reason, and because methods that can reliably detect the presence of 20 ppm intact gluten in fermented or hydrolyzed foods are not currently available, we are considering several regulatory options regarding records for fermented or hydrolyzed foods or ingredients that are concentrated or dried.

One option would be to require the manufacturer of a food bearing the ''gluten-free'' claim to document that the food or ingredient is not concentrated or dried after fermentation or hydrolysis. This would preclude fermented or hydrolyzed foods or ingredients that are concentrated or dried from being in foods bearing the ''gluten-free'' claim and reduce the number of such foods labeled as ''gluten-free'' in the marketplace.

Another option would require the manufacturer of a food bearing the ''gluten-free'' claim to make and keep records documenting that the concentrated or dried fermented or hydrolyzed ingredients used in a food bearing the ''gluten-free'' claim comply with § 101.91(a)(3). This, in turn, could cause manufacturers to request records from the ingredient supplier indicating

the gluten content of the materials used in the ingredient prior to fermentation or hydrolysis, and specific information as to how the final gluten concentration of the ingredient is determined after concentration or drying.

We invite comment on these two possible options, how the options could be modified, whether another option exists, or whether it is necessary to address concentrated or dried ingredients in this regulation. We also invite comment on the potential for fermented or hydrolyzed foods made from ingredients that are concentrated or dried to contain less than 20 ppm gluten in their concentrated or dried form, how this gluten content could be verified and the potential costs associated with a new option.

II. What does the proposed rule say?

Currently, § 101.91(c) states that when compliance with § 101.91(b) (which pertains to requirements for ''gluten-free'' labeling) is based on an analysis of the food, we will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices.

The proposed rule would amend § 101.91(c) to provide alternative means for us to verify compliance for fermented or hydrolyzed foods for which appropriate scientifically valid methods that can reliably detect and quantify the presence of 20 ppm intact gluten are not currently available. If the food or the ingredients used in a food fermented or hydrolyzed by the manufacturer contained less than 20 ppm of intact gluten before fermentation or hydrolysis, then the resulting fermented or hydrolyzed food also would contain less than 20 ppm intact gluten as long as gluten was not introduced during the fermentation or hydrolysis process. For these reasons, the proposed rule would require that the manufacturer of fermented or hydrolyzed foods bearing the ''gluten-free'' claim make and keep records regarding the food demonstrating adequate assurances that the food is ''gluten-free'' in compliance with § 101.91(a)(3) 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 ingredients and bearing the ''gluten-free'' claim, the manufacturer would be required to make and keep records demonstrating with adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free'' in compliance with § 101.91(a)(3).

We would expect that, in some cases, this adequate assurance would include test results or a certificate of analysis for the food or ingredients before fermentation or hydrolysis. Other verification procedures may be appropriate in some circumstances. We expect that the accuracy and reliability of any certificate of analysis would be verified based on initial qualification and periodic requalification of the supplier through testing of the ingredient with sufficient frequency to ensure the material contains less than 20 ppm gluten. Likewise we expect that the ingredients used would be tested with sufficient frequency to ensure the material contains less than 20 ppm gluten.

The content of the records demonstrating adequate assurance that source materials are in compliance with § 101.91(a)(3) before fermentation or hydrolysis may depend on the potential for gluten cross-contact. For example, as discussed in section I.G., a manufacturer of a grain product, such as corn breakfast cereal, may keep different records than a manufacturer of a fruit-flavored yogurt product.

Specifically, the proposed rule would renumber § 101.91(c) as § 101.91(c)(1) and would create new paragraphs (c)(2), (c)(3), and (c)(4) to explain that, when an appropriate method to verify compliance with the gluten-free regulation is not available because the food is fermented or hydrolyzed or contains one or more ingredients that are fermented or hydrolyzed, the manufacturer of the food bearing the ''gluten-free'' claim must make and keep certain records. Proposed § 101.91(c)(5) would describe how FDA would evaluate compliance for distilled foods.

A. For foods fermented or hydrolyzed by the manufacturer, what records must be kept? What must the records demonstrate? (Proposed § 101.91(c)(2))

Due to the unavoidable presence of gluten that may occur through gluten cross-contact in food ingredients or during manufacturing, the proposed rule would require that the manufacturer of foods fermented or hydrolyzed by the manufacturer and bearing the ''gluten-free'' claim make and keep records. The records are to provide adequate assurance that the food or its ingredients are ''gluten-free'' in compliance with § 101.91(a)(3) before fermentation or hydrolysis and that gluten is not introduced during the manufacturing process. If the food or its ingredients comply with § 101.91(a)(3) before fermentation or hydrolysis, and gluten is not introduced during the manufacturing process, the resulting fermented or hydrolyzed food should meet the definition of ''gluten-free.''

1. What records must be kept regarding food before fermentation or hydrolysis? (Proposed § 101.91(c)(2)(i))

The records described in proposed § 101.91(c)(2)(i) must provide adequate assurance that the food or its ingredients comply with § 101.91(a)(3) before fermentation or hydrolysis. Thus, the records must provide adequate assurance that the ingredients are not gluten-containing grains (*e.g.,* spelt wheat), and are not derived from a gluten-containing grain that has not been processed to remove gluten (*e.g.,* wheat flour) or not derived from a gluten-containing grain that has been processed to remove gluten (*e.g.,* wheat starch), if the use of that ingredient results in the presence of 20 ppm or more gluten in the food. Further, the records must provide adequate assurance that any unavoidable presence of gluten in the food is below 20 ppm gluten.

The assurances could include records of test results conducted by the manufacturer or an ingredient supplier, CoAs, or other appropriate verification documentation for the food itself or each of the ingredients used in the food. We would expect manufacturers of fermented or hydrolyzed foods that bear the ''gluten-free'' claim, as part of their routine operations, to test their food or ingredients with sufficient frequency to ensure that the gluten level in the food or in each ingredient is below 20 ppm before fermentation or hydrolysis. This testing could include a single record from testing the food before fermentation or hydrolysis (*i.e.* testing milk before fermentation into yogurt), or could include separate test result records regarding each ingredient, depending on the type of food being produced.

Alternatively, as we noted in the preamble to the final rule (78 FR 47154 at 47167), manufacturers, as part of routine operations, may rely on records, such as CoAs, from their suppliers to determine that each ingredient is below 20 ppm gluten. A CoA is a document indicating specified test results performed on product(s) by a qualified laboratory that has certified these test results. A CoA should be based on initial qualification and periodic requalification of the supplier with sufficient frequency through review of the supplier's documentation and practices.

Similarly, other appropriate verification documentation could provide adequate assurance that a manufacturer has adequately ensured the food or ingredients comply with § 101.91(a)(3). We tentatively conclude

that it is appropriate to allow a manufacturer to use any means of verification that it can develop, as long as the manufacturer can document that such verification provides adequate assurance that the ingredients comply with § 101.91(a)(3). We anticipate that most manufacturers will receive at least some ingredients from outside suppliers. For ingredients that they receive from outside suppliers, manufacturers may document a visit to a supplier's facility, review a supplier's records, and review written documentation from a supplier to verify the compliance of the ingredients they receive. We invite comment on other ingredient verification methods that may be appropriate.

The proposed rule would not specify the types of records to be kept, so the manufacturer could, for example, create the records itself regarding the ingredients that it uses or, if it obtains ingredients from a supplier, maintain records or CoAs it obtains from a supplier. The types of records may also vary based on the type of food or ingredients used. For example, a manufacturer of fermented or hydrolyzed foods from non-gluten-containing grains, legumes, or seeds that are susceptible to cross-contact with gluten-containing grains bearing the ''gluten-free'' claim may be more likely to choose to obtain a CoA from the ingredient suppliers or test the ingredients before fermentation and maintain records of the test results. A manufacturer of products bearing the ''gluten-free'' claim made from inherently gluten-free ingredients, such as milk, or fruit, that have a low probability of cross-contact with gluten-containing grains, may be more likely to use other appropriate verification documentation.

2. What records must be kept to address gluten cross-contact? (Proposed § 101.91(c)(2)(ii) and (iii))

As we discussed in the preamble to the final rule (78 FR 47154 at 47173), we expect foods bearing the ''gluten-free'' claim to be manufactured using whatever controls are necessary to prevent cross-contact with all gluten sources and to ensure that any amount of gluten that may be present in the food from gluten cross-contact is as low as possible and that the food has less than 20 ppm gluten.

To help address potential gluten cross-contact during the manufacturing process, proposed § 101.91(c)(2)(ii) and (iii) would require that a manufacturer wishing to use a ''gluten-free'' claim on a product that they ferment or hydrolyze make and keep records that provide adequate assurance that:

- The manufacturer has adequately evaluated their processing for any potential for gluten cross-contact during the manufacturing process; and
- where the potential for gluten cross-contact has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.

We expect manufacturers of foods bearing the ''gluten-free'' claim to take proper precautions to reduce the potential for gluten cross-contact of food, food ingredients, or food-contact surfaces. This may include careful examination of all phases of their operations, including, for example, transportation and storage of ingredients and finished products and the use of additional manufacturing controls that can prevent gluten cross-contact situations. For example, manufacturers may use physical barriers (such as walls, curtains, or distance) or air handling as a means of isolating the production line and by cleaning and sanitizing equipment between production runs.

In order to provide adequate assurance that they have evaluated their processing for the potential for gluten cross-contact, we expect manufacturers to document their determination regarding the potential for gluten cross-contact as well as the reasoning and/or support for their determination. In order to provide adequate assurance that they have implemented measures to prevent the introduction of gluten during the manufacturing process, we expect manufacturers to document the measures they are using as well as how they determined what measures to use and how those measures prevent gluten cross-contact. Again, the types of records that would provide adequate assurance for ingredients with a high likelihood of gluten cross-contact, such as grains and legumes, may vary from those expected for ingredients with a lower likelihood of gluten cross-contact, such as dairy.

B. For foods that contain one or more fermented or hydrolyzed ingredients, what records must be kept? What must the records demonstrate? (Proposed § 101.91(c)(3))

When a scientifically valid method is not available that equates the test results in terms of intact gluten because the food contains one or more ingredients that are fermented or hydrolyzed, proposed § 101.91(c)(3) would require the manufacturer of such foods bearing the claim to make and keep records providing adequate assurance that that the fermented or hydrolyzed ingredients are ''gluten-free.'' When the entire food is not hydrolyzed or fermented, the analytical methods discussed in the current ''gluten-free'' regulation at § 101.91(c) would be able to detect intact gluten that had been introduced through the manufacturing process or through ingredients that were not hydrolyzed or fermented. Therefore, we are only proposing to require records regarding the specific ingredients that have been fermented or hydrolyzed.

For an ingredient that was fermented or hydrolyzed by a supplier, one way for the manufacturer of a food bearing the ''gluten-free'' claim to provide adequate assurance that the ingredient is ''gluten-free'' would be to obtain records from that supplier supporting that the ingredient meets the definition of ''gluten-free,'' including that the ingredient was manufactured or processed to avoid gluten cross-contact and to contain less than 20 ppm gluten. Adequate assurance regarding the ingredients fermented or hydrolyzed by an ingredient supplier can include documentation regarding the supplier's manufacturing procedures, records of test results from tests conducted by the ingredient supplier on the components of the ingredient before fermentation or hydrolysis, CoAs, or other appropriate documentation provided by the ingredient supplier for the fermented or hydrolyzed ingredient. As discussed previously in section II.A.1, the types of records that would provide adequate assurance for ingredients with a high likelihood of gluten cross-contact, such as grains and legumes, may vary from those expected for ingredients with a lower likelihood of gluten cross-contact, such as dairy.

Manufacturers may wish to verify the accuracy and reliability of these records by checking whether and how the supplier of the ingredient documents that the components used in the fermented or hydrolyzed ingredient each meet the definition of ''gluten-free,'' including that the supplier manufactured or processed the ingredient to avoid gluten cross-contact and contain less than 20 ppm gluten before fermentation or hydrolysis. In addition, manufacturers may wish to verify records documenting the supplier's manufacturing or processing with regard to concentration.

C. How must records be maintained and made available? (Proposed § 101.91(c)(4))

Proposed § 101.91(c)(4) would establish the timeframe for keeping

records and making them available to FDA. In brief, the proposed rule would:

- Require the records be retained for 2 years after introduction or delivery for introduction of the food into interstate commerce;
- allow records to be kept as original records, true copies, or as electronic records; and
- state that the records must be available to FDA for examination and copying during an inspection upon our request.

Proposed § 101.91(c)(4) would establish a minimum 2-year recordkeeping period because we consider 2 years to be a reasonable period of time for most foods to be available for purchase in the marketplace. Such a time period is consistent with other FDA regulations, but we invite comment on whether we should use a different recordkeeping period. In addition, the records may be kept in any format, paper or electronic, provided they contain all the necessary information. Paper records can include true copies such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records. All electronic records maintained under § 101.91 would need to comply with part 11 (21 CFR part 11). The use of electronic records is voluntary and thus, a paper record system could be used to comply with the proposed recordkeeping requirements. The proposed requirements for electronic records extend to electronic signatures. We issued final guidance for industry on this topic. The guidance, entitled ''Part 11, Electronic Records; Electronic Signatures Scope and Application,'' sets out our enforcement policies with respect to certain aspects of part 11. The guidance is available at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm.* This guidance would apply to any electronic record, including electronic signatures, established or maintained to meet a proposed requirement in this rule, if finalized as proposed. This would give manufacturers the maximum flexibility to use whatever recordkeeping system they find most appropriate. We request comment on the proposed requirements for the types of records that must be made and kept and the length of time that the records must be kept.

The proposal also would state that the records must be made available to us for examination or copying during an inspection upon request; this is consistent with our other recordkeeping regulations (see, *e.g.,* 21 CFR 111.605 and 111.610). The records would need to be reasonably accessible to FDA during an inspection at each manufacturing facility (even if not stored onsite) to determine whether the food has been manufactured and labeled in compliance with § 101.91. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible. We anticipate that manufacturers may have questions about the confidentiality of the information inspected by us under this proposal. We would protect confidential information from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and 21 CFR part 20.

D. What are the requirements for distilled products? (Proposed § 101.91(c)(5))

If good manufacturing practices are followed, the process of distillation itself removes all protein. Scientifically valid methods to measure the protein content should find no detectable protein present and thus no gluten in distilled ingredients or distilled foods. The detection of any protein indicates poor manufacturing practices or controls and could point to the potential presence of gluten in the distilled ingredient or product. Likewise, the absence of protein or protein fragments in the distilled product should mean that the product's gluten level is below 20 ppm.

Consequently, proposed § 101.91(c)(5) would provide that, when a food or ingredient bearing the ''gluten-free'' claim is distilled, we will evaluate compliance by verifying the absence of protein in the food or ingredient using a scientifically valid method that can reliably detect the presence or absence of protein or protein fragments in the food. When choosing a method that will verify the absence of protein, among the factors that need to be considered is the sensitivity of the test method for this purpose, such as a limit of detection as close to zero as possible.

The detection of any protein or protein fragments in the food or ingredient may indicate poor manufacturing controls and indicate the presence of gluten in the distilled ingredient or product. We invite comment, especially including data, concerning the effectiveness of good manufacturing practices on distillation. We also invite comment, especially including data, concerning the effectiveness of other processes that can be used to remove gluten from food ingredients or food products. We also invite comment on measures food manufacturers of distilled products or products containing distilled ingredients can take to ensure that the distilled product or distilled ingredients do not contain protein or protein fragments.

E. What are the conforming changes? (Proposed § 101.91(b)(1) and (2))

The proposed rule would make two conforming changes to § 101.91(b)(1) and (2). In brief, § 101.91(b)(1) states that a food that bears the claim ''gluten-free'' in its labeling and fails to meet § 101.91(a)(3) (the definition for the term ''gluten-free'') will be deemed misbranded. Section 101.91(b)(2) creates a similar requirement if the food bears the claim ''no gluten,'' ''free of gluten,'' or ''without gluten'' and fails to meet § 101.91(a)(3). Because proposed § 101.91(c)(2) through (4) would establish requirements by which we would determine whether fermented foods, hydrolyzed foods, or foods containing a fermented or hydrolyzed ingredient are ''gluten-free'' within § 101.91, the proposed rule would amend § 101.91(b)(1) and (2) to add, ''if applicable, paragraphs (c)(2) through (4) of this section'' to the requirements that must be met if the food is not to be deemed misbranded.

F. Effective and Compliance Dates

We are proposing that the compliance date for any final rule resulting from this rulemaking be 1 year from the date of its publication. We recognize that we usually establish a uniform compliance date for food labeling changes that occur between specific dates. For example, January 1, 2016, is the next uniform compliance date for food labeling changes for food labeling regulations issued between January 1, 2013, and December 31, 2014 (77 FR 70885, November 28, 2012). In this case, however, we believe there is sufficient justification for establishing the compliance date of 1 year after the date of publication of a final rule, rather than use the next uniform compliance date for other food labeling changes that we periodically establish for such changes.

We believe that 12 months from the date of publication of the final rule for gluten-free labeling of fermented or hydrolyzed foods is sufficient time for manufacturers of fermented or hydrolyzed foods to review their products to ensure that these foods comply with that final rule or to remove ''gluten-free'' or similar claims from the label if their foods do not comply. This period of 12 months is consistent with what we have used in the past for compliance with the requirements of voluntary food labeling claims. We believe that waiting until FDA's next uniform compliance date would create

an unnecessary delay in the enforcement of a final rule because fermented or hydrolyzed foods bearing the voluntary label claim ''gluten-free'' that do not comply with FDA's requirements for use of the term ''gluten-free'' could have an adverse public health impact on persons with celiac disease who may be consuming those foods.

Therefore, we propose to establish the compliance date to enforce the provisions of a final rule for the gluten-free labeling of fermented or hydrolyzed foods as 1 year after the date of publication of the final rule in the **Federal Register**. By that time, manufacturers of fermented or hydrolyzed foods labeled with the ''gluten-free'' claim would have to comply with the final rule. We also propose an effective date of 30 days after publication in the **Federal Register**.

III. What is our legal authority for this proposed rule?

Section 206 of FALCPA directs the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, to issue a proposed rule to define, and permit use of, the term ''gluten-free'' on the labeling of foods. Section 403(a)(1) of the FD&C Act states that, ''A food shall be deemed to be misbranded if its labeling is false or misleading in any particular.'' In determining whether food labeling is misleading, section 201(n) of the FD&C Act explicitly provides for consideration of the extent to which the labeling fails to reveal facts ''material with respect to the consequences which may result from the use of the [food] to which the labeling * * * relates under * * * such conditions of use as are customary or usual.'' Section 701(a) of the FD&C Act vests the Secretary (and by delegation, FDA) with authority to issue regulations for the efficient enforcement of the FD&C Act. Consistent with section 206 of FALCPA and sections 403(a)(1), 201(n), and 701(a) of the FD&C Act, we are proposing requirements for the use of the term ''gluten-free'' for hydrolyzed and fermented foods.

The proposed rule would establish requirements concerning records necessary to ensure compliance with our ''gluten-free'' labeling regulation for fermented or hydrolyzed food or that which contains a fermented or hydrolyzed ingredient. For these foods, there is no scientifically valid analytical method available that can reliably detect and accurately quantify the equivalent of 20 ppm intact gluten in the food. In enacting FALCPA, Congress recognized the importance to individuals with celiac disease of avoiding gluten (section 202(6)(B) of FALCPA). Therefore, defining the requirements for using the term ''gluten-free'' in the labeling of fermented or hydrolyzed foods is needed to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled.

We are proposing requirements for manufacturers to make and keep records containing information that provides adequate assurance that their food complies with the definition of ''gluten-free,'' including information that they gather or produce about their ingredients and the details of their manufacturing practices. These proposed record requirements would help ensure that the use of the term ''gluten-free'' is accurate, truthful, and not misleading based on information known to the manufacturer that FDA would not otherwise be able to access and to facilitate efficient and effective action to enforce the requirements when necessary. Our authority to establish records requirements has been upheld under other provisions of the FD&C Act where we have found such records to be necessary (*National Confectioners Assoc.* v. *Califano,* 569 F.2d 690, 693–94 (D.C. Cir. 1978)). The records we propose to require are only for foods for which an adequate analytical method is not available. The records would allow us to verify that the ''gluten-free'' claim on foods that are hydrolyzed or fermented or contain hydrolyzed or fermented ingredients is truthful and complies with the requirements of the definition. Thus, the proposed records requirements would help in the efficient enforcement of the FD&C Act.

The authority granted to us under sections 701(a), 403(a)(1), and 201(n) of the FD&C Act not only includes authority to establish records requirements, but also includes access to such records. Without such authority, we would not know whether the use of the term ''gluten-free'' on the label or in the labeling of these foods is truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act (21 U.S.C. 331(a)). Thus, to determine whether the food is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be made and kept under sections 403(a)(1), 201(n), and 701(a) of the FD&C Act. Failure to make and keep records and provide the records to FDA, as described in proposed § 101.91(c)(4), would result in the food being misbranded under sections 403(a)(1) and 201(n) of the FD&C Act.

IV. What is the analysis of impacts—Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 16). FDA believes that the proposed rule will not be an economically significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 16), which is available to the public in the docket for this proposed rule at *http://www.regulations.gov* (enter Docket No. FDA–2014–N–1021), and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses may need to implement a number of new testing and recordkeeping activities, FDA acknowledges that the proposed rule, if finalized, will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual

effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule, if finalized, is not a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule, if finalized, will not result in a 1-year expenditure that would exceed this amount.

E. Public Access to the Analyses

The analyses that FDA has performed in order to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) are available to the public in the docket for this proposed rule (Ref. 16) at *http://www.regulations.gov* (enter Docket No. FDA–2014–N–1021).

V. The Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in this section of the document with an estimate of the annual recordkeeping burden. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recordkeeping Requirements for Gluten-Free Labeling of Fermented or Hydrolyzed Foods.

Description of Respondents: 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.''

Description: If the rule is finalized as proposed, we would require manufacturers of food products covered by the rule to make and keep records providing adequate assurance that: (1) The food is gluten-free before fermentation or hydrolysis; (2) the manufacturer has evaluated the potential for cross-contact with gluten during the manufacturing process; and (3) if necessary, measures are in place to prevent the introduction of gluten into the food during the manufacturing process.

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 this 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. Records would need to be reasonably accessible at each manufacturing facility and could be examined periodically by FDA inspectors during an inspection to determine whether the food has been manufactured and labeled in compliance with § 101.91 Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible.

We estimate the burden of this collection of information as follows: We base our estimates of the average burden per recordkeeping on our experience with good manufacturing practices used to control the identity and composition of food and to limit contaminants and prevent adulteration. The hour estimates for the recordkeeping burdens presented here 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.

Our estimates of the numbers of manufacturers/recordkeepers reported in column 2 of tables 1 and 2 are based on the number of food products that would be covered by the proposed rule. We searched the FoodEssentials database (Ref. 3) 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 about 2,500 products that would be affected by the proposed rule. 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 do not have any data about how many products are 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 (Ref. 17) 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 first year burden of the proposed rule. 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 ($1{,}250 \times 7 = 8{,}750$), 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 ($1{,}250 \times 0.7 = 875$), 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 ($5{,}000 \times 1 = 5{,}000$), 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 their incoming ingredients or obtain Certificates of Analysis from their ingredient suppliers. A manufacturer may test their ingredients for gluten by sending ingredient samples to a testing company or by using test kits to test ingredient samples on site at their facility. Test kits would first undergo method validation for the testing situation in which they are to be used (Ref. 18). 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 first-year burden only.

After the first year of testing, we assume the 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 testing burdens. We estimate that an average of two ingredients per product would be tested in this manner. Most foods affected by this proposed rule 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 their ingredients and production facilities for gluten and would incur additional testing burdens as a result of the proposed rule. For these manufacturers, obtaining a method extension for a test kit would be a first year burden of the proposed rule. 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 ($1{,}250 \times 14 \times (5 \div 60) = 1{,}453$) 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 ($1{,}250 \times 14 = 17{,}500$). These tests have an average cost of $84.33, which means that the estimated capital costs related to this first year paperwork burden is about $1.5 million ($17{,}500 \times \$84.33 = \$1{,}475{,}833$) as reported in table 1, row 2.

We estimate that, as a first year burden of the proposed rule if finalized, all 5,000 manufacturers would begin retaining records of the method extension tests. We estimate that it would take a manufacturer 30 minutes per record, for a total of 35,000 hours ($5{,}000 \times 14 \times 0.5 = 35{,}000$), as reported in table 1, row 3.

We estimate that testing ingredients on a regular basis would be a recurring burden of the proposed rule, if finalized, for the 1,250 manufacturers not currently testing their ingredients and production facilities for gluten. We estimate that 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 file the test results. We estimate that the burden of collecting samples for these tests would be 4,358 hours ($1{,}250 \times 21 \times (5 \div 60) = 4{,}358$), as reported in table 2, row 3. We estimate that this proposed rule, if finalized, would result in manufacturers using 52,500 test kits each year ($1{,}250 \times 42 = 52{,}500$). These test kits have an average cost of $11, which means that the estimated capital costs related to this recurring paperwork burden is about $0.6 million ($52{,}500 \times \$11 = \$577{,}500$), 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 ($5{,}000 \times 42 \times 0.5 = 105{,}000$), 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 ($1{,}250 \times 2 \times (5 \div 60) = 208$), 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 ($1{,}250 \times 2 = 2{,}500$). 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 ($2{,}500 \times \$84.33 = \$210{,}833$), 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 ($5{,}000 \times 2 \times 0.5 = 5{,}000$), as reported in table 2, row 6.

TABLE 1—ESTIMATED FIRST YEAR RECORDKEEPING BURDEN

Activity/Proposed 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Capital costs (USD Millions)
Developing an SOP for gluten control; proposed 101.91(c)(2) and (3).	1,250	1	1,250	7	8,750	0
Collecting samples for testing; proposed 101.91(c)(2) and (3).	1,250	14	17,500	0.083 (5 minutes)	1,453	$1.5
Maintaining records of method extension tests; proposed 101.91(c)(2) and (3).	5,000	14	70,000	0.5 (30 minutes) ..	35,000	0
Total					45,203	$1.5

There are no operating or maintenance cost associated with this collection information.

TABLE 2—ESTIMATED RECURRING RECORDKEEPING BURDEN

Activity/Proposed 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Capital costs (USD Millions)
Updating SOP for gluten control; proposed 101.91(c)(2) and (3).	1,250	1	1,250	0.7 (42 minutes) ..	875	0
Maintaining records of the updated SOP for gluten control; proposed 101.91(c)(2) and (3).	5,000	1	5,000	1	5,000	0
Collecting samples for test kit testing; proposed 101.91(c)(2) and (3).	1,250	42	52,500	0.083 (5 minutes)	4,358	$0.6
Maintaining records of test kit test results; proposed 101.91(c)(2) and (3).	5,000	42	210,000	0.5 (30 minutes) ..	105,000	0
Collecting samples for testing by an outside lab; proposed 101.91(c)(2) and (3).	1,250	2	2,500	0.083 (5 minutes)	208	$0.2
Maintaining records of testing by an outside lab; proposed 101.91(c)(2) and (3).	5,000	2	10,000	0.5 (30 minutes) ..	5,000	0
Total					120,441	$0.8

[1] There are no operating or maintenance costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by January 19, 2016, to the Office of Information and Regulatory Affairs, OMB.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Recordkeeping Requirements for Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods.'' These requirements will not be effective until we obtain OMB approval. We will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

VI. What is the environmental impact of this rule?

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. What are the federalism impacts of this rule?

We have analyzed the proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of Executive Order 13132 requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Here, as in the final rule published in the August 5, 2013, issue of the **Federal Register** (78 FR 47154 at 47175), we have determined that certain narrow exercises of State authority would conflict with the exercise of Federal authority under the FD&C Act.

In section 206 of FALCPA, Congress directed us to issue a proposed rule to define and permit use of the term ''gluten-free'' on the labeling of foods, in consultation with appropriate experts and stakeholders, to be followed by a proposed rule for the use of such term in labeling. In the preamble to the proposed rule regarding the ''gluten-free'' labeling of foods (72 FR 2795 at 2813 through 2814), we indicated that we had consulted with numerous experts and stakeholders in the proposed rule's development and in the final rule we determined that certain narrow exercises of State authority would conflict with the exercise of Federal authority under the FD&C Act. Different and inconsistent amounts of gluten in foods with ''gluten-free'' labeling result in the inability of those

individuals with celiac disease who adhere to a gluten-free diet to avoid exposure to gluten at levels that may result in adverse health effects. ''Gluten-free'' labeling, for purposes of this discussion, also includes the use of the terms ''no gluten,'' ''free of gluten,'' and without gluten,'' as indicated in § 101.91(b)(2). There is a need for national uniformity in the meaning of the term ''gluten-free,'' which includes the manner in which the definition is enforced, so that most individuals with celiac disease can make informed purchasing decisions that will enable them to adhere to a diet they can tolerate without causing adverse health effects and can select from a variety of available gluten-free foods.

This proposed rule would establish additional requirements for manufacturers of hydrolyzed and fermented foods or foods that contain hydrolyzed and fermented ingredients wishing to use the terms ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' on their products, thus these requirements are a component of how we permit the use of the ''gluten-free'' claim. If States were able to establish different requirements regarding what manufacturers of hydrolyzed and fermented foods would need to demonstrate in order to use the term ''gluten-free,'' then individuals with celiac disease would not be able to rely on a consistent meaning for that term and thereby use the term to identify appropriate dietary selections. As a result, individuals with celiac disease may unnecessarily limit their food choices, or conversely, select foods with levels of gluten that are not tolerated and that may cause adverse health effects. Food manufacturers, if confronted by a State or various State requirements that adopted different requirements for hydrolyzed and fermented foods than this proposed rule, might decide to remove the ''gluten-free'' label, and such a result would make it more difficult for individuals with celiac disease to identify foods that they can tolerate and achieve a dietary intake from a variety of foods to meet an individual's nutrient needs. Moreover, consistent requirements regarding the way compliance with the final rule is determined, including the records that would need to be maintained in order for a hydrolyzed or fermented food manufacturer to use the ''gluten-free'' claim and the use of a scientifically valid method to detect the absence of protein to determine compliance for distilled products, enables us to more efficiently enforce the use of the ''gluten-free'' claim across all hydrolyzed and fermented foods to ensure labels bearing a ''gluten-free'' claim are truthful and not misleading.

Therefore, the objective of this proposed rule is standardizing use of the term ''gluten-free'' in the labeling of hydrolyzed and fermented foods so that foods with this claim in labeling, and foods with a claim of ''no,'' ''free of,'' and ''without'' gluten, which connote a similar meaning to that of ''gluten free,'' are used in a consistent way and will therefore prevent consumer confusion and assist individuals with celiac disease to make purchasing decisions.

Section 4(c) of Executive Order 13132 instructs us to restrict any Federal preemption of State law to the ''minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated.'' The proposed rule meets the preceding requirement because it would preempt State law narrowly, only to the extent required to achieve uniform national labeling with respect to the requirements related to the use of the term ''gluten-free,'' as well as the terms ''no gluten,'' ''free of gluten,'' or ''without gluten'' on hydrolyzed and fermented foods. As we explain later in this section, we are proposing to preempt State or local requirements only to the extent that they are different from the requirements in this section related to the use of the terms ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' for hydrolyzed and fermented foods. In addition, we cannot foresee every potential State requirement and preemption that may arise if a State requirement is found to obstruct the federal purpose articulated in this proposed rule. This proposed rule, like the final rule, is not intended to preempt other State or local labeling requirements with respect to other statements or warnings about gluten. For example, a State would still not be preempted from requiring a statement about the health effects of gluten consumption from hydrolyzed and fermented foods on persons with celiac disease or information about how the food was processed.

Section 4(d) of Executive Order 13132 states that when an Agency foresees the possibility of a conflict between State law and federally protected interests within the Agency's area of regulatory responsibility, the Agency ''shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.'' Section 4(e) of Executive Order 13132 provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA's Division of Federal and State Relations will invite the States' participation in this rulemaking by providing notice via fax and email transmission to State health commissioners, State agriculture commissioners, and State food program directors as well as FDA field personnel of the publication of the proposed rule.

In 2009, the President issued a memorandum entitled ''Preemption'' (74 FR 24693, May 22, 2009). The memorandum, among other things, instructs Agencies to ''not include in regulatory preambles statements that the department or agency intends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation'' and ''not include preemption provisions in codified regulations except where such provisions would be justified under legal principles governing preemption, including the principles outlined in Executive Order 13132''. Because of the May 22, 2009, memorandum we explain in detail the principles underlying our conclusion that this proposed rule may result in preemption of State and local laws under a narrow set of circumstances and describe how the final rule's codified provision regarding preemption, which is now § 101.91(d), would apply to hydrolyzed and fermented foods.

Under the Supremacy Clause of the Constitution (U.S. Constitution; Art. VI, clause 2), State laws that interfere with or are contrary to Federal law are invalid. (See *Gibbons* v. *Ogden,* 22 U.S. (9 Wheat.) 1, 211 (1824).) Federal preemption can be express (stated by Congress in the statute) or implied. Implied preemption can occur in several ways. For example, Federal preemption may be found where Federal law conflicts with State law. Such conflict may be demonstrated either when ''compliance with both federal and state [law] is a physical impossibility'' (*Florida Lime and Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132, 142–143 (1963)), or when State law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'' (*Crosby* v. *Nat'l Foreign Trade Council,* 530 U.S. 363, 372–74 (2000) (citing *Hines* v. *Davidowitz,* 312 U.S. 52, 67 (1941))). State law is also preempted if it interferes with the methods by which a Federal law is designed to reach its goals. (See *Int'l Paper Co.* v. *Ouellette,* 479 U.S. 481, 494 (1987); *Michigan Canners & Freezers Ass'n* v. *Agricultural*

Marketing & Bargaining Bd., 467 U.S. 461, 477–478 (1984).)

Additionally, '' 'a federal agency acting within the scope of its congressionally delegated authority may preempt state regulation' and hence render unenforceable state or local laws that are otherwise not inconsistent with federal law'' (*City of New York* v. *FCC,* 486 U.S. 57, 63–64 (1988) (quoting *Louisiana Public Service Comm'n* v. *FCC,* 476 U.S. 355, 369 (1986)). ''Federal regulations have no less preemptive effect than federal statutes'' (*Fidelity Federal Savings and Loan Ass'n* v. *de la Cuesta,* 458 U.S. 141, 153 (1982)).

When an Agency's intent to preempt is clearly and unambiguously stated, a court's inquiry will be whether the preemptive action is within the scope of that Agency's delegated authority (*Capital Cities Cable, Inc.* v. *Crisp,* 467 U.S. 691, 700 (1984); *Fidelity Federal Savings,* 458 U.S. at 154). If the Agency's choice to preempt ''represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute [the regulation will stand] unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned'' (*United States* v. *Shimer,* 367 U.S. 374, 383 (1961)). In *Hillsborough County,* the Supreme Court stated that FDA possessed the authority to issue regulations preempting local laws that compromise the supply of plasma and could do so (*Hillsborough County, Fla.* v. *Automated Medical Laboratories, Inc.,* 471 U.S. 707, 721 (1985)). We believe we have similar authority to preempt State and local laws and regulations to the limited extent that they permit use of ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' for hydrolyzed and fermented foods differently from our proposed rule because different State or local requirements would be contrary to the Congressional directive for us to define and permit use of the term ''gluten-free.''

State or local laws or regulations that permit use of ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' differently from our proposed rule could frustrate the ability of most consumers to identify gluten-free foods and avoid adverse health effects and deter manufacturers from applying a ''gluten-free'' label to their foods. With the proposed rule, consumers throughout the United States can understand what is required to use the term ''gluten-free'' on a hydrolyzed or fermented packaged food. The proposed rule will also allow us to enforce more efficiently the definition on product labels of hydrolyzed and fermented foods, and manufacturers will be able to comply with a single set of requirements, which may lead to greater use of this voluntary labeling.

Therefore, we intend to preempt State or local requirements only to the extent that they are different from the proposed requirements related to the use of the terms ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' on fermented or hydrolyzed foods, including the requirement to make and keep certain records and the use of a scientifically valid method to detect the absence of protein for distilled foods. There is no proposed change to § 101.91(d) regarding preemption, but these new proposed requirements in § 101.91(c) would become part of the requirements covered by § 101.91(d).

VIII. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Ciclitira, P. J., D. Evans, and N. Fagg, ''Clinical Testing of Gliadin Fractions in Coeliac Patients,'' *Clinical Science,* 66: 357–364, 1984.

2. Garber, E. A. E., Memorandum to the Administrative Record, ''Standards Used to Detect and Quantify Fermented and Hydrolyzed Gluten in Foods,'' August 25, 2015.

3. FoodEssentials. Product Label Database. Online version available at: *http://labelbase.foodessentials.com/index.jsp.*

4. Belitz, H.-D., W. Grosch, and P. Schieberle, *Food Chemistry,* Berlin: Springer, pp. 141–142, 2009.

5. Ciccocioppo, R., A. Di Sabatino, and G. R. Corazza, ''The Immune Recognition of Gluten in Coeliac Disease,'' *Clinical and Experimental Immunology,* 140(3):408–416, 2005.

6. Mena, M. C., M. Lombardia, A. Hernando, et al., ''Comprehensive Analysis of Gluten in Processed Foods Using a New Extraction Method and a Competitive ELISA Based on the R5 Antibody,'' *Talanta,* 91(15):33–40, 2012, available at *http://dx.doi.org/10.1016/j.talanta.2011.12.073.*

7. Kohler, P., T. Schwalb, U. Immer, et al., ''AACCI Approved Methods Technical Committee Report: Collaborative Study on the Immunochemical Determination of Partially Hydrolyzed Gluten Using an R5 Competitive ELISA,'' *Cereal Foods World,* 58(3):154–158, 2013.

8. Codex Alimentarius Commission, ''Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (Codex Standard 118–1979),'' Rome, Italy, pp. 1–3, 2008; available at *http://www.codexalimentarius.org/download/standards/291/CXS_118e_2015.pdf.*

9. Garber, E. A. E., Memorandum to the Administrative Record, ''ELISA Methods Used to Detect Gluten in Foods,'' August 25, 2015.

10. Garber, E. A. E., Memorandum to the Administrative Record, ''Use of Proline Endopeptidases to Make Gluten Containing Products Safe for Consumption by Individuals With Celiac Disease,'' August 25, 2015.

11. Panda, R., et al. ''Effects of a Proline Endopeptidase on the Detection and Quantification of Gluten by Antibody-based Methods During the Fermentation of a Model Sorghum Beer.'' *Journal of Agriculture and Food Chemistry,* November 7, 2015 (web), accessed at *http://pubs.acs.org/doi/abs/10.1021/acs.jafc.5b04205.*

12. Fellows, P.J., ''Chapter 4-Evaporation and Distillation,'' *Food Processing and Technology—Principles and Practice* (3d Edition). Woodhead Publishing, 2009. Online version available at *http://app.knovel.com/hotlink/toc/id:kpFPTPPE14/food-processing-technology/food-processing-technology.*

13. Food and Drug Administration, Compliance Policy Guide Sec. 525.825, ''Vinegar Definitions—Adulteration With Vinegar Eels,'' available at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074471.htm.*

14. Merriam-Webster.com, Merriam-Webster, n.d. Web, available on January 30, 2014, available at *http://www.merriam-webster.com/dictionary/malt vinegar.*

15. United States Department of Agriculture, ''Federal Grain Inspection Service,'' dated September 1997 and revised April 2004, available at *http://www.gipsa.usda.gov/Publications/fgis/broch/fgisbrochure.pdf.*

16. FDA, ''Preliminary Regulatory Impact Analysis of Gluten-Free Labeling of Fermented or Hydrolyzed Foods,'' Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, July 2014, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/.*

17. Eastern Research Group, 2010 Nationwide Survey of Food Industry Safety Practices, Draft final report, January 10, 2011, ERG for FDA under Contract No. 223–01–2461, task order 7.

18. Thompson, Tricia, ''Should Manufacturers & Consumers Use Lateral Flow Devices (EZ Gluten) to Test Food for Gluten?'' Online version available at *http://www.glutenfreedietitian.com/should-manufacturers-consumers-use-lateral-flow-devices-ez-gluten-to-test-food-for-gluten/.*

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is proposed to be amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. In § 101.91, revise paragraphs (b)(1), (b)(2), and (c) to read as follows:

§ 101.91 Gluten-free labeling of food.

* * * * *

(b) *Requirements.* (1) A food that bears the claim ''gluten-free'' in its labeling and fails to meet the requirements of paragraph (a)(3) of this section and, if applicable, paragraphs (c)(2) through (4) of this section will be deemed misbranded.

(2) A food that bears the claim ''no gluten,'' ''free of gluten,'' or ''without gluten'' in its labeling and fails to meet the requirements of paragraph (a)(3) of this section and, if applicable, paragraphs (c)(2) through (4) of this section will be deemed misbranded.

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(c) *Compliance.* (1) When compliance with paragraph (b) of this section is based on an analysis of the food, FDA will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices, including both raw and cooked or baked products.

(2) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food is fermented or hydrolyzed, the manufacturer of such foods bearing the claim must make and keep records regarding the fermented or hydrolyzed food demonstrating adequate assurance that:

(i) The food is ''gluten-free'' in compliance with paragraph (a)(3) of this section before fermentation or hydrolysis;

(ii) The manufacturer has adequately evaluated their processing for any potential for gluten cross-contact; and

(iii) Where a potential for gluten cross-contact has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.

(3) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food contains one or more ingredients that are fermented or hydrolyzed, the manufacturer of such foods bearing the claim must make and keep records demonstrating adequate assurance that that the fermented or hydrolyzed ingredients are ''gluten-free'' as described in paragraph (c)(2) of this section.

(4) Records necessary to verify compliance with paragraphs (c)(2) and (3) of this section must be retained for at least 2 years after introduction or delivery for introduction of the food into interstate commerce and may be kept as original records, as true copies, or as electronic records. Manufacturers must provide those records to us for examination and copying during an inspection upon request.

(5) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food is distilled, FDA will evaluate compliance with paragraph (b) of this section by verifying the absence of protein in the distilled component using scientifically valid analytical methods that can reliably detect the presence or absence of protein or protein fragments in the food.

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Dated: November 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29292 Filed 11–17–15; 8:45 am]

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2510

RIN 1210–AB71

Savings Arrangements Established by States for Non-Governmental Employees

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Proposed rule.

SUMMARY: This document contains a proposed regulation under the Employee Retirement Income Security Act of 1974 (ERISA) setting forth a safe harbor describing circumstances in which a payroll deduction savings program, including one with automatic enrollment, would not give rise to an employee pension benefit plan under ERISA. A program described in this proposal would be established and maintained by a state government, and state law would require certain private-sector employers to make the program available to their employees. Several states are considering or have adopted measures to increase access to payroll deduction savings for individuals employed or residing in their jurisdictions. By making clear that state payroll deduction savings programs with automatic enrollment that conform to the safe harbor in this proposal do not establish ERISA plans, the objective of the safe harbor is to reduce the risk of such state programs being preempted if they were ever challenged. If adopted, this rule would affect individuals and employers subject to such laws.

DATES: Written comments should be received by the Department of Labor on or before January 19, 2016.

ADDRESSES: You may submit comments, identified by RIN 1210–AB71, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: e-ORI@dol.gov.* Include RIN 1210–AB71 in the subject line of the message.
- *Mail:* Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Attention: State Savings Arrangements Safe Harbor.

Instructions: All submissions must include the agency name and Regulatory Identification Number (RIN) for this rulemaking. Persons submitting comments electronically are encouraged to submit only by one electronic method and not to submit paper copies. Comments will be available to the public, without charge, online at *www.regulations.gov* and *www.dol.gov/ebsa* and at the Public Disclosure Room, Employee Benefits Security Administration, U.S. Department of Labor, Suite N–1513, 200 Constitution Avenue NW., Washington, DC 20210. WARNING: Do not include any personally identifiable or confidential business information that you do not want publicly disclosed. Comments are public records and are posted on the Internet as received, and can be retrieved by most internet search engines.

FOR FURTHER INFORMATION CONTACT: Janet Song, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500; or Jim Craig, Office of the Solicitor, Plan Benefits Security Division, (202) 693–5600. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

A. Background

Approximately 68 million US employees do not have access to a retirement savings plan through their employers.[1] For older Americans,

[1] Copeland, Craig, Employment-Based Retirement Plan Participation: Geographic Differences and Trends, 2013, Employee Benefit Research Institute,