has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Regulatory Findings

The FAA has determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2020–16–04 Pacific Aerospace Limited: Amendment 39–21188; Docket No. FAA–2020–0711; Project Identifier MCAI–2020–00719–A.

(a) Effective Date

This airworthiness directive (AD) becomes effective September 2, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pacific Aerospace Limited Model 750XL airplanes, serial numbers 101 through to 215, 220, 8001, and 8002, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

(e) Reason

This AD was prompted by an incorrect illustration of the screw jack assembly in the airplane maintenance manual, thus causing potential errors with installation. The FAA is issuing this AD to require an inspection of the flap screw jack assembly to verify proper configuration of the assembly and make the correction if found improperly installed. This unsafe condition, if not addressed, could cause fatigue failure of a flap screw jack, which could result in a failure of the flap actuator to fully extend the flaps during the completion of a final approach, a longer landing distance, and consequent runway overrun condition.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (2) of this AD.

(1) Within 20 hours time-in-service after September 2, 2020 (the effective date of this AD), inspect the left hand (LH) and right hand (RH) flap screw jack assemblies for proper installation by following the Accomplishment Instructions, paragraphs A.1) through A.3), of Pacific Aerospace Mandatory Service Bulletin (MSB) PACSB/XL/117, Issue 2, dated August 21, 2019 (PACSB/XL/117, Issue 2). If a flap screw jack assembly is not properly installed as shown in figures 1 and 2 of PACSB/XL/117, Issue 2, before further flight, comply with the Accomplishment Instructions, Part B, of PACSB/XL/117, Issue 2.

(2) As of September 2, 2020 (the effective date of this AD), do not install a LH flap screw jack assembly P/N 11–45621–1 or RH flap screw jack assembly P/N 11–45622–1 on any airplane, unless it is installed in accordance with the Accomplishment Instructions, Part B, of PACSB/XL/117, Issue 2.

(g) Credit for Previous Actions

You may take credit for the actions required by paragraph (f)(1) of this AD if you performed those actions before the effective date of this AD using Pacific Aerospace MSB PACSB/XL/117, Issue 1, dated June 7, 2019.

(h) Special Flight Permit

Special flight permits may be issued may be issued for the purpose of operating the airplane to a location where the requirements of this AD can be performed with the following limitations: Flights must not carry passengers.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, Small Airplane Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Mike Kiesov, Aerospace Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: *mike.kiesov@faa.gov*. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(j) Related Information

Refer to mandatory continuing airworthiness information (MCAI) New Zealand Civil Aviation Authority AD No. DCA/750XL/38A, dated September 5, 2019, for related information. You may examine the MCAI on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0711.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Pacific Aerospace Mandatory Service Bulletin PACSB/XL/117, Issue 2, dated August 21, 2019.

(ii) [Reserved]

(3) For Pacific Aerospace Limited service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; phone: +64 7843 6144; fax: +64 7843 6134; email: *pacific@aerospace.co.nz;* internet: *https://www.aerospace.co.nz/*.

(4) You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *https://www.regulations.gov* by searching for Docket No. FAA–2020–0711.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued on July 29, 2020.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–17607 Filed 8–12–20; 8:45 am]

BILLING CODE 4910–13–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: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to establish requirements

concerning ''gluten-free'' labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These requirements f 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.'' Currently, FDA knows of no scientifically valid analytical method effective in detecting and quantifying with precision the gluten protein content in fermented or hydrolyzed foods in terms of equivalent amounts of intact gluten proteins. Thus, we plan to evaluate compliance of such fermented or hydrolyzed foods that bear a ''gluten-free'' claim 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 need to provide adequate assurance that the food or ingredients used in the food are ''gluten-free'' before fermentation or hydrolysis. Once we identify that a scientifically valid method has been developed that can accurately detect and quantify gluten in fermented or hydrolyzed foods or ingredients, it would no longer be necessary for the manufacturer of foods bearing the ''gluten-free'' claim to make and keep these records. In addition, because currently there is no scientifically valid analytical method effective in detecting and quantifying the gluten protein content in fermented or hydrolyzed foods the final rule requires the manufacturer of these kinds of 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, the final rule requires manufacturers of foods that contain fermented or hydrolyzed ingredients and bear the ''gluten-free'' claim to make and keep records that demonstrate with adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free'' in compliance with the 2013 gluten-free food labeling final rule. Finally, this final rule states that we will 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:

Effective date: This rule is effective October 13, 2020.

Compliance date: The compliance date of this final rule is August 13, 2021.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: With regard to the final rule: Carol D'Lima, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., Rm. 4D–022, College Park, MD 20740, 240–402–2371, *Carol.Dlima@fda.hhs.gov.* With regard to the information collection: 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:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Final 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. Relevant educational materials are available on FDA's website at *https://www.fda.gov/food/food-labeling-nutrition/gluten-free-labeling-foods.* 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 2013 gluten-free food labeling final rule). The 2013 gluten-free food labeling 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 when compliance with the rule is based on an analysis of the food, we will use a scientifically valid method that is suitable for the reliable detection of 20 parts per million (ppm) gluten in the food and has been validated extensively for the detection of gluten in both raw and cooked or baked products (§ 101.91(c)). In the context of this rule for the Gluten-Free Labeling of Fermented or Hydrolyzed Foods, the limit for gluten refers to intact gluten. We established this 20 ppm limit for 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 or hydrolyzed foods have advanced, currently, we know of no scientifically valid analytical method effective in detecting and quantifying with precision the gluten protein content in fermented or hydrolyzed foods in terms of equivalent amounts of intact gluten. Thus, alternative means are necessary to verify compliance with the provisions of the 2013 gluten-free food labeling final rule for fermented or 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.

B. Summary of the Major Provisions of the Final Rule

Section 101.91 (21 CFR 101.91) defines the term ''gluten-free'' to mean that the food bearing the claim does not contain: (1) An ingredient that is a gluten-containing grain; (2) an ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten; or (3) an ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food; or inherently does

not contain gluten, and that any unavoidable presence of gluten in the food is below 20 ppm gluten. A food that bears the claim ''no gluten,'' ''free of gluten,'' or ''without gluten'' in its labeling and fails to meet the requirements for the ''gluten-free'' claim will be deemed to be misbranded. This final rule amends § 101.91(c) to provide alternative means for FDA to verify compliance based on records that are maintained by the manufacturer of the fermented or hydrolyzed food bearing the ''gluten-free'' claim and made available to us for inspection and copying.

This final rule requires that, for foods that are fermented or hydrolyzed and bear the ''gluten-free'' claim, the manufacturer must have records that demonstrate with 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. (A CoA is a document indicating specified test results performed on product(s) by a qualified laboratory that has certified the test results.) Alternatively, adequate assurance can include results of tests on the food itself, rather than the ingredients, before fermentation or hydrolysis of the food. In addition, the final rule requires documentation by the manufacturer that any potential for gluten cross-contact has been adequately assessed, and where such a potential has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process. Also, for foods containing one or more fermented or hydrolyzed ingredients and bearing the ''gluten-free'' claim, manufacturers must make and keep records demonstrating with adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free'' under § 101.91(a)(3) before fermentation or hydrolysis and the potential for gluten cross-contact has been adequately assessed, and where such potential has been identified, measures have been implemented to prevent introduction of gluten during the ingredient manufacturing process). This includes, but is not limited to, CoAs or other appropriate verification documentation from the ingredient suppliers and/or results of testing conducted by the ingredient suppliers.

The final rule also requires that the manufacturer retain records for at least 2 years after introduction or delivery for introduction of the food into interstate commerce. The final rule allows 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 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 final rule also provides that we will 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.

C. 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 (FD&C Act) (21 U.S.C. 343(a)(1), 321(n), and 371(a)), we are issuing 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.

D. Costs and Benefits

Full compliance with this final rule would have annualized costs of about $7 million to $11 million per year at 3% discount rate and annualized costs of $7 million to $11 million at 7% discount rate. For the rule to break-even with costs, the annualized benefits would need to be at least $8.8 million at a 3% discount rate and a $9.1 million at a 7% discount rate. Based on our simulation analysis, the rule would break-even with primary cost estimates discounted at 7% if at least 0.07% of estimated individuals with celiac disease following a gluten-free diet benefit from the rule each year.

II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation	What it means
ANPRM	Advance Notice of Proposed Rulemaking.
CPG	Compliance Policy Guide.
E.O.	Executive Order.
FALCPA	Food Allergen Labeling and Consumer Protection Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
GMP	Good Manufacturing Practice.

III. Background

A. Need for the Regulation/History of This Rulemaking

Celiac disease is a hereditary, chronic inflammatory disorder of the small intestine triggered by the ingestion of certain proteins referred to as gluten, which occur 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 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.

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 2013 gluten-free food labeling final rule, which is codified at § 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 2013 gluten-free food labeling final rule does not require manufacturers who label their foods as ''gluten-free'' to test those foods for the presence of gluten. However, they may choose to do so to ensure that the food does not contain 20 ppm or more gluten. The regulation provides that, when compliance with [the rule] 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, 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 any 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)).

Through comments we received in response to the proposed rule for gluten-free labeling of foods that appeared in the **Federal Register** of January 23, 2007 (72 FR 2795) and to a related notice reopening of the comment period that 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 we 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 those foods contained <20 ppm gluten. We 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. We requested comments on this proposed approach as well as on whether we also should require these manufacturers to maintain records on test methods, protocols, and results and to make these records available to us 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'' (78 FR 47154 at 47165).

Although test methods for the detection of gluten fragments in fermented or hydrolyzed foods have advanced, as of August 13, 2020, we know of no scientifically valid analytical method effective in detecting and quantifying with precision the gluten protein content in fermented or hydrolyzed foods in terms of equivalent amounts of intact gluten proteins. Sandwich Enzyme-Linked Immunosorbent Assay (ELISA)-based methods are not effective in detecting and quantifying gluten proteins that are no longer intact as a result of fermentation or hydrolysis since the method requires at least two epitopes to work. Competitive ELISA-based methods that recognize a single epitope have been developed and may eventually overcome the detection problems encountered using current sandwich ELISA-based assays with fermented or hydrolyzed food. While some studies have validated the reproducibility of competitive ELISA-based test methods, the lack of appropriate calibration standards or suitable reference materials make accurate quantification of gluten content difficult. This uncertainty creates problems in equating these test results to an equivalent amount of intact gluten in the fermented or hydrolyzed product. Without reference standards to gauge the response for detection and quantification of gluten to produce fermented or hydrolyzed products, such quantification is uncertain and potentially inaccurate (Ref. 2). Thus, we need other means to verify compliance for these foods.

B. What did we propose to do?

In the **Federal Register** of November 18, 2015 (80 FR 71990), we published a proposed rule to establish requirements concerning ''gluten-free'' labeling for foods that are fermented, hydrolyzed, or distilled, or that contain fermented, hydrolyzed, or distilled ingredients. In brief, we proposed to evaluate compliance with the 2013 gluten-free food labeling final rule of such fermented or hydrolyzed foods that bear a ''gluten-free'' claim 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 food is ''gluten-free'' in compliance with the 2013 gluten-free food labeling final rule before fermentation or hydrolysis. In addition, we proposed to 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, we proposed to require manufacturers of foods that contain fermented or hydrolyzed ingredients and bear the ''gluten-free'' claim to make and keep records that demonstrate with adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free'' in compliance with § 101.91. Finally, we proposed to 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. We proposed to revise § 101.91(b)(1), (b)(2), and (c) to state that when a scientifically valid method is not available because the food or ingredient is fermented or hydrolyzed, the manufacturer of such foods bearing the claim must make and keep records regarding the fermented or hydrolyzed food that demonstrate: (1) Adequate assurance that the food is ''gluten-free'' before fermentation or hydrolysis; (2) the manufacturer has adequately evaluated their processing for any potential for gluten cross-contact; and (3) 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. For foods for which a scientifically valid method to detect and quantify gluten is not available because the food is distilled, compliance would be evaluated by verifying the absence of protein (and thus gluten) 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.

IV. Legal Authority

We are issuing this final rule under section 206 of FALCPA which directs the ''Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders,'' to ''issue a 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 that are material with respect to the consequences which may result from the use of the food to which the labeling relates under 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 establishing requirements for the use of the term ''gluten-free'' for fermented and hydrolyzed foods.

Because there is no scientifically valid analytical method available that can both reliably detect and accurately quantify the equivalent of 20 ppm intact gluten in foods that are fermented or hydrolyzed, or that contain fermented or hydrolyzed ingredients, we are establishing requirements for manufacturers to make and keep records containing information that provide 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 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, 693–694 (D.C. Cir. 1978)).

The final rule requires records only for foods for which an adequate analytical method is not available. The records will allow us to verify that the ''gluten-free'' claim on foods that are fermented or hydrolyzed, or contain fermented or hydrolyzed ingredients, is truthful and complies with the requirements of the definition. 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 authority to 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 § 101.91(c)(4), would result in the food being misbranded under sections 403(a)(1) and 201(n) of the FD&C Act.

V. Comments on the Proposed Rule and FDA Responses

A. Introduction

We received over 500 comments on the proposed rule. We received comments from consumers; consumer groups; trade organizations; industry; public health organizations; public advocacy groups; and other organizations. We have numbered each comment to help distinguish among different topics. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment letter and designated them as distinct comments for purposes of our responses. The number assigned to each comment topic is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

B. Comments and FDA Responses

1. Request for Exemption for Inherently Gluten-Free Ingredients and Enzymes

(Comment 1) Several comments stated that the rule would have the unintended consequence of prohibiting certain inherently gluten-free foods and ingredients from bearing a ''gluten-free'' claim. The comments said that the added recordkeeping requirements were an unnecessary burden on manufacturers and that, in other cases, it might be impossible to request records from remote geographic regions for commodity items that are fermented immediately after harvest (*e.g.,* cocoa beans). The comments pointed out that some ingredients are at low risk of contact with gluten-containing grains at harvest as well as across the supply chain. The comments stated that FDA should make clear in the preamble to the final rule that inherently gluten-free foods, such as milk and dairy ingredients, vanilla beans, enzymes (grown on media containing gluten), flavor extracts, and cocoa beans, that have a low risk of gluten cross-contact are exempt from the final rule. The comments requested that proposed § 101.91(c)(3) not apply to foods containing fermented or hydrolyzed ingredients derived from foods that are inherently ''gluten-free'' and do not have a known or reasonable probability of gluten cross-contact. Alternatively, some comments suggested that we revise the rule to apply only to fermented foods produced from gluten-containing grains or having a known or reasonably foreseeable risk of cross-contact with a gluten-containing grain (*e.g.,* gluten-free beers). The comments suggested that we define ''fermented food'' for the purposes of this section as ''a food or ingredient derived from a gluten-containing grain by fermentation.''

The comments also stated that, if we could not create an exemption, we should clarify that testing is not required for inherently gluten-free ingredients when there is no cross-contact with gluten-containing ingredients. Also, if testing is done, it should only be at the frequency necessary to prove the ''gluten-free'' claim and records regarding cross-contact should be flexible based on ingredients and facility. Further, the comments stated that we should clarify whether documentation providing general information on the commodity and regional growing practices in countries of origin would be sufficient to meet the ''gluten-free'' claim requirements.

(Response 1) It is our experience that all foods may, at some point during manufacture, have a risk of cross-contact with a gluten-containing grain depending on manufacturer operations, sources of ingredients, movements through the supply chain and distribution, etc. There may be inherently gluten-free foods or ingredients that still do not meet the definition of ''gluten-free'' due to cross-contact with gluten that leads to gluten content in the food that is at or above 20 ppm. Conversely, there also may be inherently gluten-free foods that have some cross-contact with gluten-containing products but are still able to bear the ''gluten-free'' claim because the presence of gluten in the food due to cross-contact is less than 20 ppm. Just as we concluded in the preamble to the 2013 gluten-free food labeling final rule (78 FR 47154 at 47168), all food bearing a ''gluten-free'' claim, regardless if they are inherently gluten-free or not, must meet the definition of ''gluten-free.'' In 2015, we stated in the preamble to the proposed rule for gluten-free labeling of fermented or hydrolyzed foods that the specific types of records that would provide adequate assurance that fermented or hydrolyzed ingredients with a high likelihood of gluten cross-contact, such as grains and legumes, may differ from the records that would provide adequate assurance for ingredients with a lower likelihood of gluten cross-contact, such as dairy (80 FR 71990 at 71996 through 71998). 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 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 low probability of cross-contact with gluten-containing grains may be more likely to use other appropriate verification documentation. Thus, we decline to modify § 101.91(c)(3) to exclude any group of foods or ingredients because doing so does not consider the possibility of cross-contact.

We also decline to define the term ''fermented food'' as a food or ingredient derived only from a gluten-containing

grain by fermentation. The final rule is intended to cover all foods that are fermented or contain fermented ingredients and bear the term ''gluten-free,'' not just those from gluten-containing grains. Regardless of whether the food that is subjected to fermentation contains gluten, we cannot exclude the possibility that the food could be exposed to gluten due to cross-contact. It is important that all manufacturers who choose to use the ''gluten-free'' claim on their foods that are fermented or contain fermented ingredients evaluate their process for potential gluten cross-contact.

As requested by a comment, we are clarifying that the final rule does not require testing of ingredients. The final rule requires manufacturers to adequately evaluate their processing for any potential for gluten cross-contact. Such assessment involves evaluation of each individual manufacturing process to find out if there is a known or reasonably foreseeable risk of cross-contact with gluten-containing grains and maintenance of records to indicate that measures have been implemented to prevent the introduction of gluten into the food during the manufacturing process. As noted in the preamble to the 2015 proposed rule, we are aware that some foods and ingredients are more at risk than others (80 FR 71990 at 71996 through 71998). The manufacturer is best suited to decide how to adequately evaluate any potential for gluten cross-contact during its manufacturing process as well as the measures that should be taken to prevent the introduction of gluten into the food during that manufacturing process. The final rule requires that manufacturers of food products covered by the rule make and keep records providing adequate assurance that: (1) The food is ''gluten-free'' before fermentation or hydrolysis; (2) the manufacturer has adequately 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. In some cases, adequate assurance may be provided through testing the ingredients when there is a scientifically valid method that can reliably detect the presence of 20 ppm gluten. Testing should indicate that foods or ingredients contain less than 20 ppm gluten before fermentation or hydrolysis. To help address potential gluten cross-contact during the manufacturing process, the final rule, at § 101.91(c)(2) and (3), requires that manufacturers of a fermented or hydrolyzed product who wish to use a ''gluten-free'' claim make and keep records that provide adequate assurance that they have carefully evaluated their processing for any potential for gluten cross-contact, and where the potential exists, manufacturers have implemented measures to prevent the introduction of gluten into the food. Through this process, a manufacturer can assure that the food or its ingredients comply with § 101.91(a)(3) before fermentation or hydrolysis. As specified in the preamble to the 2015 proposed rule (80 FR 71990 at 71996 through 71998), the records providing adequate assurance that the food is ''gluten-free'' before fermentation or hydrolysis could include records of test results conducted by the manufacturer or an ingredient supplier, CoA, 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 the sufficient frequency to ensure that the gluten level in the food or in each ingredient is below 20 ppm before fermentation or hydrolysis. Alternatively, as we noted in the preamble to the 2013 gluten-free food labeling 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. Similarly, for ingredients received from outside suppliers, manufacturers may document a visit to a supplier's facility, a review of supplier's records, or a review of written documentation from a supplier to verify the compliance with § 101.91(a)(3) for these ingredients. We find it is appropriate to allow a manufacturer to use any means of verification they develop, if the manufacturer can document that such verification provides adequate assurance that the ingredients comply with § 101.91(a)(3). We do not specify the types of records to be kept, so the manufacturer could, for example, create records regarding the ingredients used or maintain records or CoAs obtained from a supplier.

As we discussed in the preamble to the 2013 gluten-free food labeling final rule (78 FR 47154 at 47173), we expect foods bearing the ''gluten-free'' claim to be manufactured using the controls necessary to minimize cross-contact with all gluten sources to ensure that any amount of gluten in the food from gluten cross-contact is as low as possible and that the food has less than 20 ppm gluten. Also, we would accept information on growing practices and product segregation as records to meet the requirements of this final rule.

(Comment 2) Several comments expressed concerns regarding some aspects of the proposed rule as it could relate to enzymes. For example, some comments stated that commercial enzymes are often produced by microbes grown on media containing wheat and that these enzymes are considered to be processing aids when used in other foods produced by fermentation. The comments said that very little gluten protein (if transferred to the food by the enzyme) may survive the fermentation process. Therefore, the comments said these enzymes should not be covered under the rule. The comments stated that the production of enzymes includes a bacterial fermentation step, but the enzymes themselves are not fermented or hydrolyzed. The comments noted that the final product is purified to remove extraneous materials and claimed that very small amounts of their enzyme products are used in food processing and, therefore, would not present a health risk to patients with celiac disease. Finally, the comments explained that wheat is not used by the enzymes that form the final product and the enzymes do not contain gluten; thus, according to the comments, the enzymes should not be classified as fermented or hydrolyzed, and we should exempt the enzymes from the rule and allow foods produced with the use of such enzymes to bear a ''gluten-free'' claim if the foods meet the ''gluten-free'' definition under § 101.91(a)(3).

(Response 2) The issue of purity and potential carry-over of growth media containing gluten is a valid concern for both the manufacturers and consumers with celiac disease. Wheat may be present in any carried-over nutrient media used to grow the microbes, and the gluten in the media may be subjected to proteolytic digestion (hydrolysis) making its quantity and biological activity hard to confirm using currently available technology. Further, it is likely that these properties will vary with the specific production process (*e.g.,* type of microbe grown, temperature, incubation period, etc.). We agree that the enzymes produced in this manner are not themselves fermented; however, the gluten that may possibly be present in the enzyme may be hydrolyzed due to fermentation. An important consideration is the amount of potential carryover and how much of the enzyme ingredient is used in the production of the final food product. Because these factors may vary

considerably, we decline to exempt enzymes from the rule.

Finally, we disagree with the comments' assertions that, because wheat is not used by the enzymes that form the final product, the enzymes do not contain gluten. Section 101.91(a)(3) requires some means of demonstrating that the final product has been processed to remove gluten to a level below 20 ppm. During the enzyme production process, the microbes make use of wheat in the nutrient medium, and any gluten present, because of the carry-over described in the preceding paragraph, may have undergone alterations, such as protein fragmentation and deamidation, during the bacterial fermentation step. We do not know how these changes affect the immunopathogenicity and other properties of gluten, and it is not clear whether the means of measuring compliance with the 2013 gluten-free food labeling final rule for intact gluten would be sufficient to safeguard consumers with celiac disease. Thus, until this is known, the final rule is 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.''

(Comment 3) One comment regarding the effects of various processing and treatment technologies noted that it was important to distinguish between those that actually remove gluten and those that modify or cleave the protein molecules without actually removing anything from the food or ingredient. The comment provided an example of production of wheat starch that involves a step in which a protein (gluten)-enriched fraction is physically separated from a protein depleted (potentially gluten-free) starch fraction. In this case, gluten has been removed. When a food or ingredient is treated by fermentation or hydrolysis, it is only possible to state that the gluten has been modified, not removed.

(Response 3) We agree that there is a difference between physical removal and modification (processing) of gluten to generate a product that does not contain any immunopathogenic elements of concern to consumers with celiac disease. When physically removing the gluten, the question is whether all of the gluten has been removed so that there is no trace left that might cause an adverse health event. Modification of the gluten is not definitive unless it is possible to demonstrate that all of the modified gluten or its protein components are no longer harmful for individuals with celiac disease.

2. Innovation in Developing Methods for Fermented, Hydrolyzed, or Distilled Foods

(Comment 4) A few comments stated that a valid method exists to quantify gluten in a product that has been fermented or hydrolyzed, like beer, and pointed to the R5 Competitive ELISA test with inactivated protease enzyme.

(Response 4) When compliance with § 101.91(b) 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, cooked, or baked products (§ 101.191(c)). As stated in the 2011 notice and the 2013 gluten-free food labeling final rule, a scientifically valid method for purposes of substantiating a ''gluten-free'' claim for food matrices where formally validated methods (*e.g.,* that underwent a multi-laboratory performance evaluation) do not exist is one 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 (76 FR 46671 at 46673; 78 FR 47154 at 47165). The R5 Competitive ELISA test has potential as a quantitative method, and we acknowledge that, under the appropriate test conditions, the R5 Competitive ELISA can generate reproducible results. The commercial R5 Competitive ELISA marketed for the detection of hydrolyzed (or fermented) gluten has, by design, an advantage over sandwich ELISA-based methods by not requiring the presence of two antigenic epitopes (antibody binding sites) to detect the presence of gluten peptides. Further, because the immunopathogenesis associated with celiac disease only requires a single immunopathogenic element, the R5 Competitive ELISA is theoretically more appropriate as an assay.

However, as currently designed, the R5 Competitive ELISA method is not suitable for the detection and quantification of gluten in any fermented or hydrolyzed food (*e.g.,* beer, yogurt). The lack of appropriate reference standards for the detection and quantification of gluten subjected to fermentation or proteolysis (hydrolysis) makes the results generated by the R5 Competitive ELISA difficult, if not impossible, to interpret. As currently supplied, the calibration standard in the R5 Competitive ELISA is allowed to proceed for a specified amount of time at a specific temperature. If the hydrolytic conditions (time, temperature, or composition under which the hydrolysis is occurring) associated with the production of the sample being analyzed were different from those used to make the calibration standards, the peptide profile is likely to be different, and the assay is unlikely to generate accurate results. The Association of Official Analytic Chemists Official Methods of Analysis (AOAC OMA) First Action award to the R5 Competitive ELISA stated that the hydrolyzed gluten being used as a calibration standard may not be suitable, and users should establish their own standards before relying on the calibration standard (Ref. 3). Specifically, minor fluctuations in temperature and time, as well as the specifics of the proteolysis, could result in a different range of peptides, making the calibration standards not suitable.

Further, it is not known how to interpret the immunopathogenicity based on the amount and profile of gluten peptides detected. The threshold of 20 ppm gluten was based on studies examining the immunopathogenicity of intact gluten. Whether the biological activity on a per mg basis is the same for gluten peptides, as was measured with intact proteins, is unknown; the answer may depend on the peptide profile.

Thus, we have concerns regarding the use of the R5 Competitive ELISA in the detection of gluten in fermented or hydrolyzed foods or ingredients because of the challenge in demonstrating that it is suitable for the intended purpose of interpreting the immunopathogenicity based on the amount and profile of gluten peptides detected and whether the method performs reliably (*i.e.,* is a scientifically valid method). While the method may perform reproducibly as indicated by the American Association of Cereal Chemist International (AACCI) validation (Ref. 4), it does not mean that the method is suitable for the intended purpose of detecting and quantifying, with sufficient accuracy, the gluten protein content in fermented and hydrolyzed foods, or assessing the immunopahogenicity or equivalent amount of intact gluten proteins.

Finally, the procedure of adding a controlled amount of an artificially prepared hydrolysate to food as required by the testing protocol (a process called ''spiking'') may give an inaccurate reading because it does not reflect the assay's ability to detect gluten that has been added to the food before processing and hydrolyzed during production. For this reason, it is

important that, whenever possible, methods be validated using gluten that is added to the food before processing. The inability to detect any gluten using the R5 Competitive ELISA (below the limit of detection) is not an indication of complete elimination or even a reduction of gluten. Another complexity is that not all the immunopathogenic sequences of gluten have been identified. Further, the R5 antibody does not recognize all immunopathogenic sequences (*e.g.,* glutenin-derived) and, therefore, gluten could be present in a form that is not detectable (Ref. 5).

(Comment 5) One comment stated that the proposed rule would require gluten to be measured using scientifically valid methods. The comment would have us revise the rule to address the fact that there are many different test methods and that they vary in their ability to provide accurate and precise data. The comment suggested that, instead of requiring that testing labs merely use ''scientifically valid'' test methods, we require that the methods are fully validated, thereby establishing performance reliability (the consistency or reproducibility of the test).

(Response 5) The ideal test method for detecting and quantifying the gluten content of feremented or hydrolyzed foods is a scientifically valid method that is suitable for the intended purpose and has been extensively, preferably multi-laboratory validated. However, multi-laboratory validation is sometimes conducted for conditions that are not suitable for the intended purpose (not scientifically valid). For example, in the R5 Competitive ELISA, which has undergone multi-laboratory validation for use in the quantitative analysis of fermented or hydrolyzed gluten, the calibration standard often does not represent the peptide repertoire being measured and, thereby, is not suitable for fermented or hydrolyzed foods or ingredients. Further, validation should focus on realistic samples. Instead, the R5 Competitive ELISA validation employed a calibration standard to which a controlled amount of substance, as required by protocol, was added into several samples; as such, the recoveries and performance of the assay were not reflective of the analysis of realistic samples. The R5 Competitive ELISA is not the only example of a method that has been promoted for use in an analysis of gluten in fermented or hydrolyzed foods, but it is mentioned here because it has been promoted for use in the quantitative analysis of fermented or hydrolyzed gluten. Although an AOAC Official Method is often a good indicator of reliability (not necessarily 'suitability for purpose' beyond the specifics described in the validation report), there are other organizations, such as the American Society for Testing and Materials (ASTM), that may develop methods that perform reliably and may be appropriate for testing gluten in fermented or hydrolyzed foods.

Other governmental agencies and industry may adopt their own procedures for testing gluten in hydrolyzed and fermented foods as well. The focus should be on using the most appropriate, scientifically valid method that meets the manufacturer's needs. Realizing insufficiencies of existing validation methods, we established our own validation protocols. Our validation protocols focus on the detection and quantification of analytes under realistic conditions (such as using a standard that has been spiked before any food processing instead of simply spiking the standard into the final food product). Once a method has been validated, the method can only be used for a novel food following evaluation and validation of the method performance with the specific food matrix.

(Comment 6) Several comments stated that the proposed rule does not offer flexibility for scientific innovation and, therefore, unintentionally prevents fermented and hydrolyzed foods from benefiting from scientific advancements that are very likely to be achieved. One comment stated that the proposed rule is overly restrictive, shows disregard to competition and innovation, and threatens to stifle the marketplace because it fails to account for new and emerging technologies and scientific developments in this area. Other comments asserted that the rule will limit options for those suffering from gluten-related disorders.

(Response 6) As with all detection methodology, we support efforts to resolve the uncertainty issues associated with quantifying gluten fragments and interpreting results in terms of intact gluten. The preamble to the 2013 gluten-free food labeling final rule (78 FR 47154 at 47169) and this final rule reflect our support in encouraging innovation in how gluten-free products are produced and the development of new analytical methods for detecting the gluten content of foods. Other than our discussion of distillation, where testing for the absence of protein indicates compliance with the use of the term ''gluten-free,'' we deliberately did not specify analytical methods that should be used. We did this because we believe that specifying analytical methods would unnecessarily limit flexibility and possibly deter the development of new and better analytical methods as well as methods for gluten removal. In the preamble to the 2013 gluten-free food labeling final rule (78 FR 47154 at 47169), we stated that we were not specifying analytical methods in the final rule even though we had included a description of two analytical methods that met our needs for the analysis of intact gluten in the 2011 notice that reopened the comment period for the proposed rule for gluten-free food labeling of foods (76 FR 46671 at 46672). In the 2011 notice, we described the methods along with references explaining how the two methods were suitable-for-purpose and were validated. The information in the preamble to the 2013 gluten-free food labeling final rule provided extensive discussion about why we were not specifying analytical methods in order to support the development of new and better technologies and also demonstrate flexibility for foods that are not fermented or hydrolyzed by allowing stakeholders to use the methods most appropriate to fit their needs (78 FR 47154 at 47169).

More importantly, we have written the final rule in a manner that, once we identify that a scientifically valid method, pursuant to § 101.91(c)(1), has been developed that can accurately detect and quantify gluten in some or all fermented or hydrolyzed foods or ingredients, § 101.91(c)(2)–(c)(4) would no longer be applicable for those foods, and it would no longer be necessary for the manufacturer of foods bearing the ''gluten-free'' claim to make and keep the records required under § 101.91(c)(2)–(c)(4) demonstrating adequate assurance that the food meets the ''gluten-free'' definition before fermentation or hydrolysis. Should any new scientifically valid methods be developed that can accurately detect and quantify gluten in fermented and hydrolyzed foods, FDA would determine compliance in accordance with § 101.91(c)(1). (On our own initiative, we have revised § 101.91(c)(1) to state that the scientifically valid method is one that can ''reliably detect and quantify'' the presence of 20 ppm gluten. We added the words ''and quantify'' to clarify that the scientifically valid method needs to do more than detect the presence of gluten.) In addition, should any new scientifically valid methods be developed for fermented or hydrolyzed foods, we expect that we would identify the existence of such methods through guidance or other appropriate means.

Therefore, we disagree with the assertion that the final rule is overly restrictive, adversely affects competition or innovation, or fails to account for emerging technologies.

(Comment 7) One comment asked us to give insight regarding which analytical methods might be of greater utility for verifying absence of protein in distilled foods and ingredients.

(Response 7) We decline to discuss in detail the pros and cons of the various analytical methods available for verifying the absence of protein in distilled food and ingredients because the best method may depend on factors such as food matrix, the experience of the analyst, the business decision of the company, etc. Additionally, a list of methods may be misinterpreted as indicating that we consider other approaches that are not included on the list to be unacceptable or of comparatively less value or usefulness.

3. Distilled Food

(Comment 8) One comment stated that FDA claimed that there is no proof that gluten does not volatilize during the distillation process because the temperatures are not high enough to allow gluten to pass through a still. The comment went on to state that, rather than banning a ''gluten-free'' claim on any product that had not been tested for gluten, FDA should rely on existing science that proves that gluten does not pass through a distillation still and, therefore, would not end up in a distilled product. The comment said that testing every batch is a hardship on small craft and farm distillers and prevents marketing of these kind of products to those with gluten intolerance. The comment also said that we should commission a scientific study to confirm that gluten may be present in distilled spirits or that gluten does not pass through a still and, therefore, all distilled spirits do not contain gluten.

(Response 8) The comment may have misunderstood our position. We did not claim that there is no proof that gluten does not volatilize during the distillation process because the temperatures are not high enough to allow gluten to pass through a still. If good manufacturing practices are followed, the process of distillation must remove all protein (and thus gluten), regardless if the product has been distilled from gluten-containing grains. As discussed further in Response 9, distillation is considered a process to remove gluten and it is unlikely that residual gluten may be present in the final distilled products. Transfer of gluten into the distillate would only be expected to occur under poor manufacturing practices in which the initial material is splashing into the distillate due to poor design of the still. Protein testing can be done to confirm that protein (and thus gluten) is absent in the distilled product. We note that testing of each batch is not required under existing regulations, and this rule specifies the methods we will use to verify compliance for distilled foods in § 101.91(c)(5). In addition, we note that any ingredients (such as flavors) added to the distilled product would need to comply with our regulations defining ''gluten-free'' in § 101.91(a) for the finished product labeling to bear the gluten-free claim.

(Comment 9) A few comments opposed different requirements for distilled foods because, according to the comments, distilled foods have caused reactions in some people and, therefore, are not safe. The comments stated that the exception for distilled foods is in direct conflict with the gluten-free food labeling rule and creates an uneven playing field within the overall alcoholic beverages category. The comments pointed out that malt beverages or other products that have undergone a process to remove or reduce gluten content are not treated the same as distilled spirits.

One comment suggested a tiered labeling system for distilled foods with varying labels (''Gluten-free,'' ''gluten-free'' with a disclaimer, ''gluten-reduced,'' no gluten claim allowed) that allows ''gluten-free'' labeling when testing is possible with the caveat that if the starting material was a gluten-containing grain, a disclaimer is used to disclose this fact. The comment claimed that this tiered labeling standard would provide full disclosure to the consumer, place the burden on industry to provide accurate labeling, and be transparent.

(Response 9) As we explained in the preamble to the proposed rule (80 FR 71990 at 71995, 71999), while creating distilled vinegar does involve fermentation, the process of distillation heats a liquid, which vaporizes components with lower boiling points and separates them from components with higher boiling points. The remaining compounds, whose boiling points are too high to undergo vaporization, are left behind. If distillation is done properly, the process removes gluten because gluten does not vaporize. Therefore, there should not be any gluten remaining in the final distilled product. For this reason, a distilled product labeling may bear a ''gluten-free'' claim and should be safe for people with celiac disease to consume.

We also disagree that the regulations for distilled foods or ingredients is in direct conflict with our regulations defining ''gluten-free.'' Our regulations permit ingredients derived from a gluten-containing grain that has been processed to remove gluten if the use of that ingredient does not result in the presence of 20 ppm or more gluten in the food (§ 101.91(a)(3)(i)(A)(*3*)).

We are aware that the process of distillation is capable of separating gluten and other proteins from the remaining compounds and, therefore, we make this distinction for foods or ingredients that are distilled. Scientifically valid methods for protein testing can determine if a product is free of protein and, therefore, also free of gluten. Thus, we will evaluate compliance 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. Furthermore, we note that malt beverages, as defined under the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. 211(a)(7)), do not undergo distillation and, therefore, would not be subject to § 101.91(c)(5).

As for the comment regarding a tiered labeling system, to be consistent with § 101.91, which defines the term ''gluten-free,'' we decline to introduce a tiered labeling system along with a disclaimer because § 101.91(b)(2) provides for the use of the label claims ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' if the product meets the definition under § 101.91(a)(3). Use of any of these terms on products that were made from gluten-containing grains would not meet the definition of ''gluten-free'' in § 101.91(a)(3) and would, therefore, misbrand the products unless the ingredients used to formulate the food have been processed to remove gluten and the final food product contains less than 20 ppm of gluten. We note that this rule does not prohibit other truthful and not misleading labeling statements about the presence or absence of gluten in food products that do not meet a ''gluten-free'' definition, provided the statements do not expressly or implicitly suggest that the food meets FDA's ''gluten-free'' definition.

(Comment 10) One comment stated that we should revise the rule to distinguish between distilled vinegar made from raw material naturally free from gluten and vinegar made from raw material containing gluten. The comment recommended that if the original feedstock is ''gluten-free,'' then no further testing is needed. The comment pointed out that distilled

vinegar is made from distilled ethanol which is further fermented into vinegar by bacteria. Distilled ethanol is generally produced from non-gluten-containing raw material such as corn, beet or sugar cane but in some cases, also gluten-containing cereals. Vinegar itself is not distilled; only the main raw material to make the vinegar is distilled. Therefore, according to the comment, proteins and/or protein fragments may be present due to the use of yeast or yeast extract in the fermentation of distilled vinegar.

Other comments asked us how we plan to distinguish proteins or protein fragments that may originate from the ethanol feedstock from those proteins and protein fragments that may originate from the ethanol fermentation process. The comments stated that such a distinction for any protein detected is important.

(Response 10) As we explained previously in the preamble to the proposed rule (80 FR 71990 at 71995, 71999), distillation is a process capable of separating gluten and other proteins from the remaining compounds and, therefore, we make this distinction for foods or ingredients that are distilled. Due to the distillation process, no protein fragments should be in the ethanol feedstock. Scientifically valid methods for protein testing can determine if a product is free of protein and, therefore, also free of gluten. Only those vinegars made from distilled ethanol that are further processed in a manner to avoid the introduction of gluten can be considered ''gluten-free.'' As for the possible introduction of gluten from those proteins and protein fragments that may originate from the ethanol fermentation process, as with any product, it is the manufacturer's responsibility to implement measures preventing the introduction of gluten into the food elsewhere in the manufacturing process for an ingredient made ''gluten-free'' by distillation. Further, the manufacturer could request from their supplier that the raw materials, such as bacteria or yeast used in the fermentation of distilled vinegar, be ''gluten-free.'' One way this can be accomplished is by avoiding the use of bacteria grown on any gluten-containing source material or by using appropriate testing to confirm that the material (bacteria) are ''gluten-free.'' Thus, the vinegar manufacturer would have assurance that the distilled ethanol was used in a manner that prevented the introduction of gluten into the food during the manufacturing process.

Scientifically valid analytical methods are readily available to detect the presence or absence of protein and protein fragments (and thus gluten) in distilled foods. Therefore, as indicated in § 101.91(c)(5) of this final rule, we will evaluate compliance with § 101.91(b) 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.

4. Different Compliance Standard

(Comment 11) Some comments stated that the rule concludes that fermented or hydrolyzed foods should be subject to a different labeling compliance standard than other foods bearing a ''gluten-free'' claim based upon the assumption that no scientifically valid method will be developed to accurately detect the presence of gluten in these food products.

(Response 11) There is research underway within FDA and elsewhere to develop methods to accurately detect and quantify the presence of gluten in fermented or hydrolyzed foods. However, as we noted in the proposed rule (80 FR 71990 at 71991), although test methods for the detection of gluten fragments in fermented or hydrolyzed foods have advanced, there is still uncertainty in interpreting the results. The currently available test methods are not capable of producing results on a quantitative basis that equate to an equivalent amount of intact gluten, and thus, we are making available alternate means by which these kinds of foods can comply with § 101.91. Once we have identified a scientifically valid method, it would no longer be necessary for the manufacturer of foods bearing the ''gluten-free'' claim to make and keep the records required under § 101.91(c)(2)–(c)(4), and FDA would determine compliance in accordance with § 101.91(c)(1). If or when a scientifically valid method to detect and quantify the presence of gluten in fermented or hydrolyzed foods become available, we will identify this change through a guidance document or other appropriate means. In addition, FDA may consider changing our regulations if warranted.

(Comment 12) Several comments questioned whether fermented or hydrolyzed foods should be subject to a different compliance standard than other foods bearing a ''gluten-free'' claim when there is a high probability that a scientifically valid method will be developed in the very near future to accurately detect the presence of gluten in such foods. The comments suggested that we remove the reference to any particular food that is distilled, fermented, or hydrolyzed in the wording of proposed § 101.91(c)(2) through (c)(5). This would mean that the labeling requirements would apply equally to all food categories for which a scientifically valid method is not available to confirm compliance with the 20 ppm gluten threshold. The comments said this would provide FDA with the necessary compliance authority to impose a higher standard on certain foods where we determine that a valid scientific method does not currently exist. Later, when a scientifically valid analytical method is established, no regulatory amendment process would be required. The comments further explained that the proposed language does not offer any flexibility for scientific innovation in this area and unintentionally prevents this group of foods from ever benefiting from scientific advancements that are likely to be achieved.

(Response 12) When we developed the proposed rule, there were no scientifically valid methods for the purposes of analyzing fermented or hydrolyzed foods to determine compliance with § 101.91. Because, currently, there are no analytical methods to reliably detect and quantify gluten in fermented or hydrolyzed food nor methods to equate test results in terms of intact gluten, we will evaluate compliance of these foods that bear a ''gluten-free'' labeling claim with the 2013 gluten-free food labeling final rule based on records that provide adequate assurance that the foods are ''gluten-free'' before fermentation or hydrolysis. Fermented or hydrolyzed foods are subject to the same labeling compliance standards as any other food that would bear a ''gluten-free'' claim. This final rule describes how manufacturers of fermented or hydrolyzed foods or distilled foods would be able to demonstrate compliance and how FDA will evaluate compliance. For this reason, we decline to remove reference to distilled foods and fermented or hydrolyzed foods from § 101.91(c)(2) through (c)(5). Further, as we noted in Response 6, if or when a scientifically valid method for fermented or hydrolyzed foods becomes available, FDA will identify such a method through a guidance document or other appropriate means. Once FDA identifies such a method, it would no longer be necessary for the manufacturer of foods bearing the ''gluten-free'' claim to make and keep the records required under § 101.91(c)(2) though (c)(4), and FDA would determine compliance with the ''gluten free'' labeling requirements under § 101.91(c)(1).

(Comment 13) One comment stated that the proposed rule appears to

impose a stricter requirement on electronic records related to the gluten-free voluntary labeling standard than the requirements for other food safety records under other regualtions. For example, the comment states that section II.C. of the proposed rule (80 FR 71990 at 71998 through 71999) indicates that electronic records, including electronic signatures, established or maintained to meet the requirements of this rule would be subject to the electronic records and electronic signatures requirements in part 11 (21 CFR part 11). However, the comment states that § 117.305(g), FDA's regulation concerning Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, establishes that electronic records established or maintained to meet the requirements of part 117 and that meet the definition of electronic records in § 11.3(b)(6), are exempt from the requirements of part 11.

(Response 13) Although the proposed rule indicated that electronic records would need to comply with part 11, we also note that the use of electronic records is voluntary and thus, a paper record system could be used to comply with the proposed recordkeeping requirements. This would give manufacturers the maximum flexibility to use whatever recordkeeping system they find most appropriate (80 FR 71999).

The final 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. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible. Compliance with FDA's regulation concerning Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food in 21 CFR part 117 has no bearing on this rule.

(Comment 14) One comment said that, in the preamble to the proposed rule, but not in the proposed codified language, FDA recognizes that there is a significant difference between fermented or hydrolyzed foods produced from gluten-containing grains and those that are not. According to the comment, proposed § 101.91(c)(2) would require the manufacturer of such foods bearing the claim to make and keep records demonstrating adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free.'' The comment said that the preamble to the proposed rule stated that ''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.'' The comment suggested that this can be interpreted as imposing a greater recordkeeping requirement on the ''low likelihood'' foods than is required in part 117, ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' (21 CFR part 117) for food safety hazard analysis. In particular, the comment said that, in § 117.130(b)(1), manufacturers only must address hazards that are ''known or reasonably likely.'' The comment said that it would be appropriate to only require records in cases where the potential presence of gluten or gluten-containing grains is ''known or reasonably likely.'' The comment stated that manufacturers should be required to document the information and process used to reach this conclusion but should not be subject to further recordkeeping requirements.

(Response 14) The comment asked that we only require records in cases where the potential presence of gluten or gluten-containing grains is ''known or reasonably likely.'' While the ''known or reasonably likely'' standard is established in part 117 for food safety hazard analysis, this final rule was specifically developed to establish the requirements for the voluntary use of the ''gluten-free'' claim that allows consumers to practice dietary avoidance and benefits individuals suffering from celiac disease. Although we acknowledge that there is a difference in the likelihood of gluten cross-contact in some fermented or hydrolyzed foods, because there is no scientifically valid method to quantify the gluten protein content in fermented or hydrolyzed foods, manufacturers who wish to produce and label such foods as ''gluten-free'' still need to make and keep records, as described in the new requirements of § 101.91(c), to provide adequate assurance of the type of ingredient used is ''gluten-free'' before fermentation or hydrolysis and to address the potential for cross-contact with gluten-containing grains or ingredients. The records for different foods can have different levels of detail needed to demonstrate compliance. As we have noted in section III.A. and elsewhere in this document, the results of current gluten test methods for fermented and hydrolyzed foods do not provide accurate quantitive results sufficient to be suitable for use with fermented or hydrolyzed foods. Thus, to evaluate compliance of such fermented and hydrolyzed foods that bear a ''gluten-free'' claim, we need to rely on records made and kept by the manufacturer providing adequate assurance that the food is ''gluten-free'' in compliance with § 101.91(a)(3) before fermentation or hydrolysis. In addition, this rule requires 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, implemented measures to prevent the introduction of gluten into the food during the manufacturing process.

It is, therefore, appropriate and reasonable to impose the recordkeeping requirement established under § 101.91(c)(4) in this final rule for fermented or hydrolyzed foods bearing a ''gluten-free'' claim to substantiate a firm's compliance with § 101.91(a). Therefore, we decline to change the rule as suggested by the comment and have finalized § 101.91(c)(4) without change.

5. ''Gluten-Free'' Labeling of Beer

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 FAA Act. Certain other beers that do not meet the definition of a malt beverage under the FAA Act (27 U.S.C. 211(a)(7)) are subject to FDA's labeling requirements. Beer manufacturers whose beers are subject to FDA's labeling requirements and do not meet the ''gluten-free'' definition are not precluded from using other statements on the label, such as a gluten statement consistent with the TTB Revised Interim Policy on Gluten Content Statements in the Labeling and Advertising of Wine, Distilled Spirits, and Malt Beverages, about processing of beers to reduce gluten (Ref. 6). However, such statements must be truthful and not misleading in accordance with our general labeling provisions in sections 403(a)(1) and 201(n) of the FD&C Act.

In the preamble to the 2013 gluten-free food labeling final rule (78 FR 47154 at 47166), we said that, under limited circumstances, we would exercise enforcement discretion with respect to the requirements for ''gluten-free'' labeling for FDA-regulated beers that already made a ''gluten-free'' claim before the rule was published and that were: (1) Made from a non-gluten-containing grain; or (2) made from a gluten-containing grain, where the beer

had been subject to processing that the manufacturer had determined would remove gluten. We said that the enforcement discretion pertained only to those beers subject to FDA's labeling requirements that made a ''gluten-free'' claim as of August 5, 2013, pending completion of the rulemaking process with respect to fermented or hydrolyzed products. We also said that any beer manufacturer that wanted to make a new ''gluten-free'' claims should contact FDA regarding the possible expansion of our consideration for the exercise of enforcement discretion related to such labeling. With the publication of this final rule, we complete the gluten-free labeling rulemaking and the enforcement discretion described in the preamble to the 2013 gluten-free food labeling final rule (78 FR 47154 at 47166) is no longer valid.

On February 11, 2014, TTB issued a revised interim policy on gluten content statements in the labeling and advertising of beverages or beers it regulates. The ''Revised Interim Policy on Gluten Content Statements in the Labeling and Advertising of Wines, Distilled Spirits, and Malt Beverages'' allows the use of the following qualifying statement to inform consumers: ''Product fermented from grains containing gluten and [processed or treated or crafted] to remove gluten. The gluten content of this product cannot be verified, and this product may contain gluten,'' or ''This product was distilled from grains containing gluten, which removed some or all of the gluten. The gluten content of this product cannot be verified, and this product may contain gluten.'' (Ref. 6).

We stated in the preamble to the proposed rule (80 FR 71990 at 71994) that, as with other foods, beers 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 (*e.g.,* wheat starch) in accordance with the provisions in the ''gluten-free'' definition before making beer, the beer may be eligible to make the claim.

As far as the claims that beer 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 gluten removal processes. We acknowledge that gluten can be at least partially broken down by several processes, including fermentation. However, as we explain in section III.A. of this rule, the presence or absence of gluten broken down in this way cannot be reliably detected with sandwich ELISA-based methods.

In the preamble to the proposed rule (80 FR 71990 at 71994), we requested comments to learn more about the efficacy of competitive ELISA-based methods, given the beer industry's practice of adding enzymes to the beer to prevent the problem of cloudiness or ''haze.'' The enzyme hydrolyzes or breaks down gluten proteins at proline residues. Thus, using 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. As we noted in the preamble to the proposed rule (80 FR 71990 at 71995), it is uncertain that cleavage at proline residues eliminates the concern for people with celiac disease because there may be immunopathogenic protein fragments still present. In other words, we do not know whether the protein fragments can trigger a reaction in people with celiac disease.

In the preamble to the proposed rule, we requested 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 (80 FR 71990 at 71995). We also were interested in scientific research regarding how we can use such test methods to determine whether 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 invited comment, including data and any information on scientific research and methods, to determine if a specific enzymatic treatment 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 proteins (80 FR 71990 at 71995).

We received several comments related to these specific questions as well as some other beer-related topics.

(Comment 15) Many comments opposed the use of the terms ''made to remove gluten,'' ''crafted to remove gluten,'' and other similar such terms on beer labels. The comments stated that such terms are not the same as ''gluten-free'' and that consumers may think they are the same, especially because these products are often marketed as ''gluten-free.'' Other comments stated that ''gluten-free'' was not the same as ''gluten-reduced,'' and that products treated to remove gluten should be clearly differentiated from those that are inherently gluten-free.

(Response 15) Our regulations at § 101.91 seek to eliminate confusing and potentially misleading language that might hinder people with celiac disease from properly identifying food safe for consumption. In the preamble to the 2013 gluten-free food labeling final rule (78 FR 47154 at 47164), we explained that, under § 101.91(b)(2), a food that bears the claim ''no gluten,'' ''free of gluten,'' or ''without gluten'' in its labeling and fails to meet the requirements for a ''gluten-free'' claim will be deemed to be misbranded.

Based upon comments that we received during a public meeting on August 19, 2005, to discuss the topic of gluten-free food labeling and comments that were submitted in writing to the related FDA Docket No. FDA–2005–N–0404 (formerly 2005N–0279), we believe that a uniform definition of the term ''gluten-free'' prevents confusion and uncertainty among both consumers and food manufacturers about what this food labeling claim means. Therefore, we have not defined the terms ''gluten-reduced,'' ''crafted to remove gluten,'' or ''made to remove gluten,'' and we do not consider those terms to be equivalent to ''gluten-free.'' Although some products may be labeled with these terms as long as the label is truthful and not misleading (*e.g.,* so as to not imply that they are gluten-free), we reiterate that consumers with celiac disease should rely only on the terms specified in § 101.91(b)(2) to indicate that a food is ''gluten-free'' or safe for them to consume.

This final rule does not change the definition of ''gluten-free,'' but only adds compliance requirements for hydrolyzed, fermented, or distilled foods.

(Comment 16) Several comments stated that it would be appropriate for beers made with gluten-containing grains to be labeled as ''crafted to remove gluten,'' along with a statement that ''the beer is fermented from grains containing gluten and crafted to remove gluten.'' The comments stated that the gluten content of the beer cannot be verified and that a statement that the beer may contain gluten is truthful, accurate, and not misleading and provides the consumer with adequate information to make a purchase decision. The comments said that our proposed rule is too narrow in focus and that TTB's Policy authorizing qualified ''crafted to remove gluten'' claims for fermented alcohol beverages made with

gluten-containing grain ingredients is appropriate. The comments said that our proposal fails to incorporate TTB's Policy requirements or distinguish between the claims that are subject to FDA's gluten-free requirements from TTB's qualified ''crafted to remove gluten'' claim. The comments strongly urged FDA to adopt the TTB Policy authorizing qualified ''crafted to remove gluten'' claims.

(Response 16) As we have noted previously, the statutory directive for this rule was to define the term ''gluten-free,'' and this rulemaking, like the 2013 gluten-free food labeling final rule, is intended to implement that statutory directive. The intent in this rulemaking is to provide an alternative for showing compliance with the ''gluten free'' definition in § 101.91(a)(3) because current analytical methods are not suitable for the quantification of gluten in fermented or hydrolyzed foods (like beer). Thus, beers under our jurisdiction that are 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 before the fermentation process to make beer, the beer may be eligible to make the claim under the final rule.

We do not agree with the comments stating we should adopt TTB's Policy. In the preamble to the proposed rule, we noted that the labeling of beer is subject to oversight by two separate federal agencies (80 FR 71990 at 71995). In addition, we stated that 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 (80 FR 71990 at 71995).

We appreciate the efforts of TTB to provide terminology for products they regulate that do not meet the definition of ''gluten-free,'' and as the proposed rule for gluten-free labeling of fermented or hydrolyzed foods clearly states, and we are reiterating here, FDA-regulated beers are not precluded from using other statements on the label, such as a gluten statement consistent with the TTB Policy (80 FR 71990 at 71995). Such statements must be truthful and not misleading. Beers that do not meet the definition of malt beverage are not subject to the labeling provisions of the FAA Act, but can be subject to the food labeling provisions of the FD&C Act and implementing regulations. This includes the provisions concerning the use of ''gluten-free'' claims, and such statements may not expressly or implicitly suggest to the consumer that the product is ''gluten-free'' when it does not meet the requirements of § 101.91.

(Comment 17) A few comments pointed out that fermented beverages are different from other foods. One comment further stated that prohibiting ''gluten-free'' claims for fermented products that are made with gluten-containing grains, without regard for whether gluten is present in the finished product, would conflict with the policy of the Codex Alimentarius [1] (Codex) on gluten claims. The comment stated that the rule does not provide clarity that fermented alcoholic beverages currently labeled as processed/treated to remove gluten in accordance with the TTB Policy will be permitted to continue being so labeled. Without clear guidance from FDA with respect to the permissibility and standards of such labeling, the comment said that the conditions may exist for potential disparate ''crafted to remove gluten'' standards to arise.

(Response 17) The Codex Standards for ''gluten-free'' labeling (see Codex Standard 118–1979, section 2.1.1b) require that foods labeled as ''gluten-free'' not contain gluten-containing grains unless they have been processed to remove gluten and the end product has less than 20 ppm gluten. Thus, contrary to the comment's assertion, our requirements are aligned with the policy of Codex on gluten claims.

As for fermented or hydrolyzed products, the final rule applies to FDA-regulated foods, including certain beers, and, as we stated in the preamble to the proposed rule, we will work with TTB on the issues associated with the ''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 (80 FR 71990 at 71995). The final rule does not redefine the term ''gluten-free'' or provide for the use of other statements, but rather the rule provides how manufacturers of foods that are fermented or hydrolyzed can comply with § 101.91.

(Comment 18) Some comments stated that the TTB Policy does not protect those with celiac disease and creates a competitive disadvantage for beers that are truly free of gluten (as opposed to having been processed in some manner to reduce gluten). According to the comments, the TTB Policy allows products made from gluten-containing grains to be labeled as being ''processed,'' ''treated,'' or ''crafted'' to remove gluten, along with a qualifying statement indicating that the product's gluten content cannot be determined, and that the product may contain gluten. The comments stated that certain companies are displaying meaningless gluten test results to their consumers. In addition, the comments expressed concern that, if TTB adopted the same approach as our rule, manufacturers will sell low gluten beers as ''gluten-free,'' and consumers will not be able to differentiate between ''gluten-free'' and ''low-gluten'' products.

(Response 18) Although TTB consults with FDA about the issuance of regulations regarding the labeling of ingredients and substances contained in alcohol beverages, as we noted in the preamble to the 2013 gluten-free food labeling final rule (78 FR 47154 at 47165), TTB, and not FDA, is responsible for the issuance and enforcement of regulations with respect to the labeling of beers that are malt beverages under the FAA Act. TTB's Policy states that, ''the term 'gluten-free' may be used on labels and in advertisements if the product would be entitled to make a gluten-free label claim under the standards set forth in the new FDA regulations at 21 CFR 101.91'' (Ref. 6).

We will continue to work with TTB on the issues associated with ''gluten-free'' labeling of beer to promote consistency in terminology to avoid label statements that are either not truthful or are misleading.

(Comment 19) One comment pointed out that proline endopeptidase (PEP) (a yeast derived enzyme used by some manufacturers to selectively degrade the haze-forming peptides and proteins present in beer) provides a suitable and convenient processing aid for preparing ''gluten-free'' barley-based beverages. The comment mentioned research done by Osman et al. 2003 (Ref. 7), which described the gradual degradation of barley proteins during the malting stage where barley glutens were likely to be digested to peptides. The comment also stated that, according to Akeroyd et al. and Panda et al. (Refs. 7 and 8), adding the enzyme during the beer fermentation phase helps to further reduce the modest gluten concentrations present in conventionally brewed beers. More specifically, the enzyme helps in destroying the minimal core sequence required for T-cell recognition. The comment also stated that if a beer shows an ELISA response below the detection level, then the absence of peptides with

[1] The Codex Alimentarius is a collection of internationally recognized standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety. *http://siweb.dss.go.th/standard/Fulltext/codex/CXS_118E.pdf.*

T-cell recognition sites is almost guaranteed. The comment said that, after using the PEP in the brewing of beer, no known immunopathogenic sequence is detected by mass spectrometry and the R5 Competitive ELISA analysis fails to detect any gluten. The comment did, however, acknowledge that a final verification on the absolute quantities of gluten present in the end product remains necessary.

(Response 19) It has been well established that barley glutens are not completely digested to amino acids during the malting and fermentation stage and that the gluten fragments are present in the final beer product (Ref. 8, Ref. 10, Ref. 11). Using mass spectrometry, multiple research groups have detected gluten peptides in conventionally brewed beer and beer brewed in the presence of PEP that has tested negative for an ELISA response because the level of gluten was below the limit of detection of ELISA test kits (Ref. 8, Ref. 9, Ref. 10, Ref. 11). The inability to detect certain known protein fragments in gluten that elicit a response in people with celiac disease does not mean that all possible fragments related to celiac disease are absent because the identities of all possible T-cell epitopes have not been established (Ref. 12). Additionally, Fiedler et al., were able to demonstrate that gluten peptides that contained immunogenic sequences knowns to be associated with celiac disease were detected in PEP-containing beer (Ref. 13). Though it is likely that PEP breaks down gluten, that is not the goal for the use of PEP. Also, the comments acknowledge, there is no scientifically valid analytical method able to quantify the gluten content in terms of equivalent amounts of intact gluten proteins.

We established the use of a 20 ppm limit as one criterion in the definition of ''gluten-free'' because 20 ppm is currently the lowest level at which analytical methods have been scientifically validated to reliably and consistently detect gluten across a range of food matrices, providing a limit for any inadvertent cross-contact with gluten during the manufacturing process. Allowing the ''gluten-free'' label claim on food whose ingredients are derived from a gluten-containing grain and have been processed to remove gluten, but not on food containing such ingredients that have not been processed to remove gluten, helps to ensure that the finished product meets the requirement that the food contain less than 20 ppm. Further, under § 101.91, gluten-containing grains (*e.g.,* wheat, rye, barley) are not to be used in the production of ''gluten-free'' products even if the concentration of gluten in the final product was less than 20 ppm.

6. Issues Outside the Scope of This Rule

Some comments pertained to matters that were outside the scope of this rule. However, we address several of these comments here.

Several comments stated that the term ''gluten-free'' should be reserved only for foods that are inherently ''gluten-free.''

We addressed this issue in the 2013 gluten-free food labeling final rule (78 FR 47154). There may be inherently gluten-free foods or ingredients that still do not meet the definition of ''gluten-free'' due to cross-contact with gluten that leads to gluten content in the food that is at or above 20 ppm. The rule defines ''gluten-free'' to mean the product does not contain a gluten-containing grain or an ingredient derived from a gluten-containing grain unless that ingredient has been processed to remove gluten and the use of that ingredient does not result in the presence of 20 ppm or more gluten in the food. Also, any unavoidable presence of gluten in a product labeled as ''gluten-free'' must be less than 20 ppm. We concluded in the preamble to the 2013 gluten-free food labeling final rule (78 FR 47154 at 47168), that all foods bearing a ''gluten-free'' claim, regardless if they are inherently gluten-free or not, must meet the definition of ''gluten-free.'' We chose not to limit the use of the term to only foods that were inherently gluten-free because such an approach could have the unintended effect of reducing the food choices available for individuals who have celiac disease, thereby reducing the variety of foods needed to meet their nutrient needs.

Other comments asked us to clarify our position on the use of barley malt and barley malt extract in foods bearing a ''gluten-free'' claim.

We note that malt syrup and malt extract are interchangeable terms for a viscous concentrate of a water extract of germinated barley, with or without a preservative. The terms barley malt or barley malt extract are used also. Malt syrup is usually a brown and viscous liquid containing varying amounts of amylolytic enzymes with plant constituents. Malt extract and malt syrup are ingredients derived from a gluten-containing grain, barley, that have not been processed to remove gluten. Food and ingredient manufacturers should be aware that malt extract and other similar malt-derived ingredients are ingredients derived from gluten-containing grains that have not been processed to remove gluten and, therefore, cannot be used in foods that bear ''gluten-free'' labeling.

One comment said that some wheat starch contains small levels of both intact and hydrolyzed gluten and asked us to clarify which methods should be used to test such products because we consider wheat starch to be ''processed to remove gluten.''

We note that wheat starch, when properly manufactured, does not involve hydrolysis of the gluten and can be protein-free. However, as we explain in the preamble to the 2007 proposed rule for gluten-free food labeling, we recognize that there may be different methods of deriving wheat starch, and that some methods may remove less gluten than others (72 FR 2795 at 2802). Therefore, § 101.91(a)(3)(i)(A)(*3*) prohibits a food that contains an ingredient that is derived from a gluten-containing grain and 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. Manufacturers who label their food as ''gluten-free'' should make certain that the food does not contain 20 ppm or more gluten, regardless of whether or not those foods contain an ingredient that is derived from a gluten containing grain that has been processed to remove gluten. We would expect manufacturers of products that they wish to label as ''gluten-free'' to use good manufacturing practices and be aware of the practices used in production of the ingredients they use in their products. Also, if the processing does involve hydrolysis resulting in hydrolyzed gluten, then the product would be subject to the requirements of this rule.

Finally, one comment asked us to clarify what government entities regulate ''gluten-free'' claim for gluten-reduced beer on restaurant menus and store shelves. We note that TTB is responsible for the labeling requirements for beers, including gluten-reduced beers, that meet the definition of malt beverage in the FAA Act (27 U.S.C. 211(a)(7)). Beers that do not meet the definition of malt beverage are not subject to the labeling provisions of the FAA Act, but are subject to the food labeling provisions of the FD&C Act and implementing regulations, including the provisions concerning the use of ''gluten-free'' or other type of gluten claims. Regarding restaurant menus that bear a ''gluten-free'' claim, we recommend that, for beers subject to the food labeling provisions of the FD&C Act and implementing regulations, restaurants use the defined food labeling

claim ''gluten-free'' to be consistent with our ''gluten-free'' definition.

VI. Effective and Compliance Dates

This rule is effective September 14, 2020. We recognize that manufacturers of fermented or hydrolyzed foods, or foods containing fermented or hydrolyzed ingredients, currently bearing a ''gluten-free'' claim may need time to review their products to ensure that these foods comply with this final rule, or to remove ''gluten- free'' or similar claims from the label if their foods do not comply.

Compliance date: Consequently, the compliance date of this final rule is August 13, 2021.

Although we are issuing the final rule after January 1, 2019, there is sufficient justification for establishing the compliance date of August 13, 2021, to enforce the provisions of this final rule, rather than January 1, 2022, which FDA established as the next uniform compliance date for other food labeling changes for food labeling regulations issued between January 1, 2019, and December 31, 2020 (83 FR 65294; December 20, 2018).

We believe that 12 months from the date of publication is sufficient time for manufacturers to review their products to ensure that these foods comply with this 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 FDA has 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 of January 1, 2022, would create an unnecessary delay in the enforcement of this final rule, as foods bearing the voluntary labeling ''gluten-free'' that do not comply with FDA's regulatory definition of ''gluten-free'' could have an adverse public health impact on persons with celiac disease who may be consuming those foods.

Therefore, we are establishing the compliance date to enforce the provisions of this final rule at August 13, 2021.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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 us 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). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is not an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small firms may have annualized costs that do not exceed one percent of their annual revenue, we certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, 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 $156 million, using the most current (2019) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure that meets or exceeds this amount in any year.

The costs of this rule are the costs to manufacturers of covered foods of testing ingredients for gluten, evaluating potential for cross-contact, if necessary developing and carrying out written standard operating procedures (SOPs) for preventing gluten cross-contact, relabeling products that cannot be brought into compliance, and maintaining records of these activities for FDA inspection. We estimate total annualized costs of $7 million to $11 million for the 3% discount rate and annualized costs ranging from $7 million to $11 million at 7% discount rate. All costs are computed in 2018-dollar values.

The benefits of this rule are health gains for people with celiac disease using ''gluten-free'' labeled foods while maintaining a gluten-free diet. To examine the potential scope of these benefits, we simulate the harm done by dietary gluten intake from a gluten-free diet before and after the rule. Due to uncertainty in this simulation analysis, we describe benefits qualitatively. For the rule to break-even with costs, the annualized benefits would need to be at least $8.8 million at a 3% discount rate and a $9.1 million at a 7% discount rate. Based on our simulation analysis, the rule would break-even with primary cost estimates discounted at 7% if at least 0.07% of estimated individuals with celiac disease following a gluten-free diet benefit from the rule each year.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

[Millions]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $ millions/ year.	.....	.....	.....	2018 2018	7 3	10 10	
Annualized Quantified	.....	.....	.....	.....	7 3		

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE—Continued

[Millions]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Qualitative	The benefits of this rule are health gains for people with celiac disease using ''gluten-free'' labeled foods while maintaining a gluten-free diet. For the rule to break-even with costs, the annualized benefits would need to be at least $8.8 million at a 3% discount rate and a $9.1 million at a 7% discount rate. Based on our simulation analysis, the rule would break-even with primary cost estimates discounted at 7% if at least 0.07% of estimated individuals with celiac disease following a gluten-free diet benefit from the rule each year.						
Costs:							
Annualized Monetized $millions/year	$9.09	$7.34	$11.46	2018	7	10	
	8.76	7.14	10.94	2018	3	10	
Annualized Quantified Qualitative					7		
					3		
Transfers:							
Federal Annualized Monetized $ millions/year.					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $ millions/year.					7		
					3		
From/To	From:			To:			
Effects:							
State, Local or Tribal Government:							
Small Business:							
Wages:							
Growth:							

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon based on 2016-dollar values. Based on these costs, this final rule would be considered a regulatory action under E.O. 13771.

TABLE 2—E.O. 13771 SUMMARY TABLE

[In $ millions 2016 dollars, over an infinite time horizon]

Item	Primary estimate (7%)	Lower estimate (7%)	Upper estimate (7%)
Present Value of Costs	$107.12	$89.37	$130.02
Present Value of Cost Savings	0	0	0
Present Value of Net Costs	$107.12	$89.37	$130.02
Annualized Costs	$7.50	$6.26	$9.10
Annualized Cost Savings	0	0	0
Annualized Net Costs	$7.50	$6.26	$9.10

The full analysis of economic impacts is available in the docket for this final rule (Ref. 14) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VIII. Analysis of Environmental Impact

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.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). 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.

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

1. 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.''

2. Description

In this final rule, we require manufacturers of certain 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 fermented or hydrolyzed food are only required to make and keep these records for the fermented or hydrolyzed ingredient. We estimate that the manufacturers can satisfy the recordkeeping requirements of this rule 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 can instead comply with this rule by obtaining and maintaining records of Certificates of Analysis (CoA), 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 for these products. Records 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 3 and 4 are based on the number of food products that are covered by the rule. Our search of FoodEssentials database was completed in November of 2017 (Ref. 15) for foods that are hydrolyzed, fermented, or contain fermented or hydrolyzed ingredients and bear the labeling claim ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten,'' and found about 2,500 products that are affected by the rule. Based on our understanding of the market and experience with the percentage of the food market covered by this database, we estimate that this database has at least half of all products that are covered by the rule, so that there are likely, at most, 5,000 products affected by the 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 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. 16) 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 manufacturers 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 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.

3. 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 is a first year burden of the rule. We estimate that it takes a facility an average of seven hours to develop an SOP for gluten control. Thus, we estimate that in the first year of compliance with this final rule, 1,250 facilities would develop an SOP for a burden of 8,750 hours (1,250 facilities × 7 hours per facility = 8,750 hours), as reported in Table 3, row 1.

Updating the facility's SOP for gluten control would be a recurring burden of the rule for the 1,250 facilities that do not currently have an SOP. We estimate that it takes a facility about 0.7 hours (42 minutes) annually to update its SOP for gluten control, for a burden of 875 hours (1,250 facilities × 0.7 hours per facility = 875 hours), as reported in table 4, row 1.

We estimate that maintaining records of their updated SOPs would be a recurring burden of this rule for all 5,000 facilities. We estimate that it takes each facility one hour annually to maintain records of its updated SOPs for gluten control, for a burden of 5,000 hours (5,000 facilities × 1 hour per facility = 5,000 hours), as reported in table 4, row 2.

4. Recordkeeping Burden Related to Testing

To demonstrate that a 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 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. 17). 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 for existing products.

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. Based on the variety of products under FDA's jurisdiction that are fermented or hydrolyzed, we estimate that an average of two ingredients per product would be tested in this manner. Most foods affected by this rule are those that contain a single fermented or hydrolyzed ingredient. As explained earlier, adequate assurance that these fermented or hydrolyzed ingredient(s) were gluten-free before that supplier performed hydrolysis or fermentation can include test results, CoAs, or other appropriate verification documentation for each of the ingredients. Other products contain multiple ingredients that would be tested before fermentation or hydrolysis.

As described above, we estimate that most manufacturers (75 percent) already have a gluten control SOP that includes testing, so they will not undertake any additional testing as a result of this rule. In the first year of compliance, we estimate that the 1,250 manufacturers not currently testing their ingredients and production facilities for gluten would incur additional testing burdens as a result of this rule. For these manufacturers, obtaining a method extension for a test kit would be a first year burden of this 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 1,458 hours (1,250 manufacturers × 14 samples per manufacturer × (5 minutes ÷ 60 minutes per hour) = 1,458 hours) as reported in Table 3, row 2. We estimate that this rule results in manufacturers conducting 17,500 laboratory tests in the first year (1,250 manufacturers × 14 samples to be tested per manufacturer = 17,500 samples to be tested). 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 tests × $84.33 per test = $1,475,833) as reported in table 3, row 2.

We estimate that, as a first year burden of this rule, all 5,000 manufacturers would begin retaining records of the method extension tests. We estimate that it takes a manufacturer 30 minutes per record, for a total of 35,000 hours (5,000 manufacturers × 14 sample records per manufacturer × 0.5 hours per sample record = 35,000 hours), as reported in table 3, row 3.

We estimate that testing ingredients on a regular basis would be a recurring burden of the rule, 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 is 4,375 hours (1,250 manufacturers × 42 test kits per manufacturer × (5 minutes per test kit ÷ 60 minutes per hour) = 4,375 hours), as reported in table 4, row 3. We estimate that this rule, results in manufacturers using 52,500 test kits each year (1,250 manufacturers × 42 test kits per manufacturer = 52,500 test kits). 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 test kits × $11 per kit = $577,500), as reported in Table 4, row 3. We estimate the burden to process and maintain records of the test results would be 105,000 hours (5,000 manufacturers × 42 test kits per manufacturer × 0.5 hours per test kit = 105,000 hours), as reported in table 4, row 4.

We estimate that a recurring burden of this rule, for all 5,000 manufacturers, is 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 is 208 hours (1,250 manufacturers × 2 tests per manufacturer × (5 minutes ÷ 60 minutes per hour) = 208 hours), as reported in table 4, row 5. We estimate that this rule results in manufacturers conducting 2,500 laboratory tests in the first year (1,250 manufacturers × 2 tests per manufacturer = 2,500 tests). 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 tests × $84.33 per test = $210,833), as reported in table 4, row 5. We estimate the burden to process and maintain records of the test results is 5,000 hours (5,000 manufacturers × 2 tests per manufacturer × 0.5 hours per test = 5,000 hours), as reported in table 4, row 6.

TABLE 3—ESTIMATED FIRST YEAR RECORDKEEPING BURDEN [1]

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; 101.91(c)(2) and (3).	1,250	1	1,250	7	8,750	0
Collecting samples for testing; 101.91(c)(2) and (3).	1,250	14	17,500	0.083 (5 minutes)	1,458	$1.5
Maintaining records of method extension tests; 101.91(c)(2) and (3).	5,000	14	70,000	0.5 (30 minutes)	35,000	0
Total					45,203	$1.5

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

TABLE 4—ESTIMATED RECURRING RECORDKEEPING BURDEN [1]

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; 101.91(c)(2) and (3).	1,250	1	1,250	0.7 (42 minutes)	875	0

TABLE 4—ESTIMATED RECURRING RECORDKEEPING BURDEN [1]—Continued

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)
Maintaining records of the updated SOP for gluten control; 101.91(c)(2) and (3).	5,000	1	5,000	1	5,000	0
Collecting samples for test kit testing; 101.91(c)(2) and (3).	1,250	42	52,500	0.083 (5 minutes)	4,375	$0.6
Maintaining records of test kit test results; 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; 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; 101.91(c)(2) and (3).	5,000	2	10,000	0.5 (30 minutes)	5,000	0
Total					120,458	$0.8

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

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this final 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 2013 gluten-free food labeling 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 2007 gluten-free food labeling proposed rule (72 FR 2795 at 2813 through 2814), we indicated that we had consulted with numerous experts and stakeholders in proposed rule's development and 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 final rule establishes additional requirements for manufacturers of fermented and hydrolyzed foods or foods that contain fermented and hydrolyzed 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'' labeling claim. If States were able to establish different requirements regarding what manufacturers of fermented or hydrolyzed 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 fermented or hydrolyzed foods than this 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 fermented or hydrolyzed 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 fermented and hydrolyzed foods to ensure labels bearing a ''gluten-free'' claim are truthful and not misleading.

Therefore, the final rule's objective is standardizing use of the term ''gluten-free'' in the labeling of fermented and hydrolyzed 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 prevent consumer confusion and help individuals with celiac disease 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 final 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 fermented and hydrolyzed foods. We intend to preempt State or local requirements only to the extent that the State or local requirements are different from the labeling requirements in this section related to the use of the terms ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' for fermented and hydrolyzed 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 rule. This rule, like the rule codified at § 101.91, is not intended to preempt other State or local labeling requirements with respect to other statements or warnings about gluten. For example, a State is not preempted from requiring a labeling statement about the health effects of gluten consumption from fermented or hydrolyzed foods on persons with celiac disease or information about how the food was processed.

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 final 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 fermented or hydrolyzed 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 fermented or hydrolyzed foods differently from our rule because different State or local labeling 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 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 this final rule, consumers throughout the United States can understand what is required to use the term ''gluten-free'' on the labeling of a fermented or hydrolyzed packaged food. This final rule will also allow us to enforce more efficiently the definition on product labels of fermented or hydrolyzed 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 these final requirements related to the use of the terms ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' on the labeling of 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 change to § 101.91(d) regarding preemption, but the new requirements in § 101.91(c) are part of the requirements covered by § 101.91(d).

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction.

Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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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 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.

* * * * *

(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 and quantify 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 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: July 29, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0249; FRL–10011–78]

Novaluron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes and modifies tolerances for residues of novaluron in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances and modifications under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2020. Objections and requests for hearings must be received on or before October 13, 2020 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0249, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Please note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2019–0249 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 13, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2019–0249, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 30, 2019 (84 FR 45702) (FRL–9998–15), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8746) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested to amend 40 CFR 180.598 by establishing tolerances for residues of the insecticide novaluron, including its metabolites and degradates, in or on the following commodities: *Brassica,* leafy greens, subgroup 4–16B at 25 parts per million (ppm); cottonseed subgroup 20C at 0.6 ppm; kohlrabi at 0.7 ppm; sunflower subgroup 20B at 0.07 ppm; tropical and subtropical, small fruit, inedible peel, subgroup 24A at 9 ppm;