Document Information

Title: NSF Protocol P404-2019 Gluten-Free	
Document #: 17591	**Revision:** 03
Status: Release	**Release Date:** 24 Apr 2019

NSF INTERNATIONAL

Protocol P404 – 2019

NSF Gluten-Free

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NSF Protocol P404

NSF Gluten-Free

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Publish Date: April 9, 2015

Revisons:

February 2017 April 2019

Published by

NSF International
PO Box 130140, Ann Arbor, Michigan 48113-0140, USA

For ordering copies or for making inquiries with regard to this Protocol, please reference the protocol title.

Printed in the United States of America.

Objectives and Disclaimers

This NSF Protocol provides basic criteria to promote and protect gluten-free integrity. Provisions for food safety have not been included in this Protocol as elements of a thorough food safety system go beyond the gluten-free requirements set forth in this document. Compliance with this Protocol does not guarantee compliance with local, state or federal regulations.

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NSF Protocol P404

Gluten-Free

1 General

1.1 Purpose

This Protocol provides a framework for the definition of requirements, evaluation and testing methods to certify products as “gluten-free”. The framework is applicable to ingredients, formulations, and processing methods and facilities used in the manufacture of products making a gluten-free claim.

NSF third party certification confirms that controls and monitoring are in place to ensure ongoing compliance with these requirements to substantiate gluten-free label claims and provide assurance to the consumer.

1.2 Scope

This certification program is intended for the manufacture and sale of gluten-free products in regions where the gluten threshold of 20 ppm is accepted as the definition of gluten-free or where there is no regulatory framework for the definition of gluten-free claims. The manufacturing of gluten-free products is confirmed through program review, third party audits, and independent product testing. Gluten content thresholds established in this Protocol have been defined to meet and exceed requirements referenced in the Gluten-Free Labeling of Foods under 21 CFR 101.91.

All foods, dietary supplements, and personal care products are eligible for certification. NSF offers third party Gluten-Free Certification globally for products, processes, and food service establishments meeting the requirements of the Protocol. At this time NSF does not offer Gluten-Free Certification for products classified as controlled substances by the DEA.

It is the responsibility of the certified operation to ensure compliance with local regulations relating to the sale of products bearing “gluten-free” claims and use of the NSF Gluten-Free certification mark.

2 References

CODEX STAN 118-1979 (2008), *Standard For Foods For Special Dietary Use For People Intolerant To Gluten*[1]

CFR Title 21, Section 101.91, *Gluten-Free Labeling Of Food*[2]

Enzyme Technical Association – 2014, *“Gluten-Free” Claim for Enzyme Dietary Supplements: Interim Guidance*[3]

[1] Codex Alimentarius. Viale delle Terme di Caracalla, 00153 Rome, Italy <www.fao.org>

[2] U.S. Food and Drug Administration. 10903 New Hampshire Avenue, Silver Spring, MD 20993 <www.fda.gov>

[3] Enzyme Technical Association. 1111 Pennsylvania Avenue, NW Washington, DC 20004-2541 <www.enzymetechnicalassociation.org/

FALCPA – 2004, *Food Allergen Labeling and Consumer Protection Act*[2]

The Center for Food Safety and Applied Nutrition – 2006, *Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food*[2]

78 FR 47154 – 2013 Food Labeling, *Gluten-Free Labeling of Foods*[2]

FDA – 2016, *Proposed Rule for Gluten-Free Labeling of Fermented or Hydrolyzed Foods*[2]

Federal Register Food Labeling – 2015, *Gluten-Free Labeling of Fermented or Hydrolyzed Foods*[2]

Time Magazine, Sifferlin, Alexandra – 2015, *Many Probiotics Contain Traces of Gluten, Study Says*[4]

3 Definitions

3.1 audit: An extensive physical examination of a facility, its equipment, and its testing procedures for the purpose of observation of practices and collection of samples to determine compliance with facility programs and structures; an evaluation of programs and systems.

3.2 batch or lot: A specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and/or is produced according to a single manufacturing order during the same cycle of manufacture.

3.3 cereal grasses: The young green plant that does not include the seed kernel or endosperm. Gluten proteins are found in the seed kernel and the endosperm but not in the stem and leaves. Examples include wheat grass, barley grass, and kamut grass.

3.4 certified entity: An organization contracting with NSF for certification and use of the gluten-free mark.

3.5 dedicated facility: A facility that only sources, stores, and produces gluten-free products or exclusively produces products that are inherently gluten-free.

3.6 dedicated production line: A production line that only produces gluten-free products or exclusively produces products that are inherently gluten-free.

3.7 distilled food: Distilled foods are formed as a result of a purification process that involves heating a liquid such that volatile components with lower boiling points are vaporized and recovered separately from nonvolatile components with higher boiling points. The remaining nonvolatile compounds, whose boiling points were too high to undergo vaporization, are removed from the distilled food. Examples of distilled foods include some vinegars and distilled water.

3.8 enzymes: A substance produced from a living organism that speeds up reactions to bring about a specific biochemical reaction.

3.9 enzymes as processing aids: Enzymes as processing aids are generally used at very low levels in the manufacturing of food products, to the extent that the enzyme itself is typically not functional in the final product. Thus the use of gluten containing substrates in the production of enzymes is likely not a significant source of gluten in the finished food product. The health risk associated with the use of gluten containing

[4] Sifferlin, Alexandra. *Many Probiotics Contain Traces of Gluten, Study Says.* (Time Magazine, 2015) <time.com/3860361/probiotics-gluten>

substrates in the production of enzymes as processing aids is low because of the very low, catalytic levels of use of those enzymes.

3.10 fermented food: A fermented food is one that has undergone a process that typically involves the conversion of complex organic compounds, especially sugars and other carbohydrates, by yeast or bacteria producing metabolic byproducts of simpler compounds such as lactic acid and ethyl alcohol, a process known as fermentation. During fermentation, proteins are broken apart into smaller groups of amino acids known as peptides. Examples of foods that are subject to fermentation during manufacturing are cheese, yogurt, vinegar, sauerkraut, pickles, green olives, beers, wine, and spirits.

3.11 final point of production: The facility responsible for the final packaging of the finished product requiring no further processing prior to sale

3.12 finished product: A product requiring no further processing prior to sale.

3.13 gluten: The proteins that naturally occur in a gluten containing grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins).

3.14 gluten containing grain: Wheat (all species), barley, rye, and all crossbred varieties (including but not limited to names such as pearl barley, malted barley, couscous, faro, triticale, spelt, durum, einkorn, semolina, kamut, bulgur, and farina).

3.15 gluten-free: The following definitions are relevant to this Protocol:

3.15.1 FDA gluten-free: Any food, cosmetic or personal care, or dietary supplement product that meets the United States Food and Drug Administration (FDA) final rule qualifications. The final rule defines "gluten-free" as meaning that the food either is inherently gluten-free; or does not contain an ingredient that is: (1) a gluten containing grain (e.g., spelt wheat); (2) derived from a gluten containing grain that has not been processed to remove gluten (e.g., wheat flour); or (3) derived from a gluten containing grain that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food. Also, any unavoidable presence of gluten in the food must be less than 20 ppm.

3.15.2 inherently gluten-free ingredient: Any raw material / commodity that is not a gluten containing grain and is direct from the farm with no processing and no risk of cross-contamination. Example: fresh red peppers or fresh basil.

3.15.3 NSF Certified Gluten-Free: Any food, personal care or cosmetic, or dietary supplement product confirmed by NSF through a system of formula and document review, facility audit and product testing to meet the following criteria:

3.15.3.1 The finished food or product must contain no more than 15 ppm of gluten.

3.15.3.2 Foods or products with the claims “no gluten,” “free of gluten,” and “without gluten” must meet the definition for “gluten-free”.

3.15.3.3 Foods or products with ingredients that are gluten containing grains that have been refined in such a way to remove the gluten may use the claim, so long as the food contains no more than 15 ppm gluten.

3.15.3.4 Foods or products shall not use the claim if they contain more than 15 ppm gluten even if confirmed to be a result of cross-contact with gluten containing grains.

3.16 Gluten-Free Compliance Plan (GCP): A management system in which gluten-free integrity is addressed and ensured through the analysis and control of biological, chemical, and physical hazards from

the production, procurement and handling of ingredient to manufacturing, distribution and consumption of the finished product.

3.17 high risk ingredients: NSF considers raw oats and cereal grasses (i.e., barley grass, wheat grass) high risk due to their potential of cross-contamination with gluten ingredients during the harvesting or manufacturing process of the raw ingredient. Additional requirements to demonstrate compliance are stated in Section 4.6.1.4.

3.18 hydrolyzed food: A hydrolyzed food is one in which a food's chemical components, such as proteins, are broken into smaller organic compounds by reaction with water. These reactions are often accelerated by enzymes. Examples of hydrolyzed foods include hydrolyzed soy protein and hydrolyzed wheat protein. Examples of foods that use hydrolyzed plant proteins as flavor enhancers include soups, chili, sauces, gravies, stews, dips, and some snacks like potato chips and pretzels.

3.19 intervening event: A step or an activity in the manufacturing process that mitigates risk of an identified hazard, especially when parallel processing certified and non-certified product in common facilities or on common equipment.

3.20 lot number: A distinctive combination of letters, numbers or symbols, or any combination thereof from which the complete history of the manufacture, processing, packaging, holding, and distribution of a batch or lot of a finished gluten-free ingredient or other material can be determined.

3.21 manufacture or manufacturing: All operations associated with the production of gluten-free ingredients or finished products including packaging, labeling, testing, and quality control of a gluten-free ingredient or finished product.

3.22 non-dedicated (or shared) facility: A facility that produces both gluten-free and gluten containing products; this may include a facility that contains dedicated equipment, or uses shared equipment.

3.23 non-dedicated production line: A production line that produces both gluten-free and gluten containing products; this may include a facility that contains dedicated equipment, or uses shared equipment.

3.24 ppm: Parts per million or mg/kg; mg of gluten per kg of material (i.e., ingredient or finished product).

3.25 processing aid: a) Substances that are added during processing but are removed with good manufacturing practices; b) substances added during processing but do not have a technical or functional effect; c) substances added for their technical or functional effect but are present at insignificant amounts. [21 CFR 101.100 (a) (3) (ii)].

3.26 products: For the purpose of this program, products include food, supplements, cosmetics, and skin care products.

3.27 prohibited grains: Grains prohibited from use in NSF Certified Gluten-Free products. This includes: wheat, rye, barley, and their related species or crossbred hybrids or any derivative; wheat, including any species belonging to the genus Triticum; rye, including any species belonging to the genus Secale; barley, including any species belonging to the genus Hordeum.

3.27.1 byproduct of prohibited grain(s): A product formulated with one or more components of the prohibited grains, such that the end product contains no more than 15 ppm of detectable gluten, or, fermented and hydrolyzed food or ingredients derived from prohibited grains must contain no more than 15 ppm of detectable gluten prior to fermentation or hydrolysis; (e.g., wheat bran or wheat starch).

3.28 ingredient: An ingredient or combination of ingredients (i.e., sub-ingredients) intended for use in the manufacture of a gluten-free product including those that may not appear in such finished product.

3.29 shared equipment: Equipment used in the manufacture of gluten-free products that is also used in the manufacture of gluten containing products.

3.30 TTB regulated products The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for enforcing laws and regulating alcohol production, importation and wholesale businesses; tobacco manufacturing and importing businesses; and alcohol labeling and advertising. At this time NSF is not offering Gluten-Free Certification to TTB regulated products.

3.31 USDA regulated products The United States Department of Agriculture (USDA) regulates meat products, poultry products, egg products (dried, frozen, or liquid eggs, with or without added ingredients), and mixed food products that generally contain more than 3% raw meat, or 2% or more cooked meat or poultry meat. Foods regulated by the USDA that are labeled gluten-free are voluntarily following the FDA's gluten-free labeling rule.

4 Gluten-free certification requirements

4.1 Documents and records

4.1.1 Documents and records must accurately describe the current gluten-free processes at the certified entity's facility. Product specific documentation in the form of product profiles, list of suppliers, and labels shall be submitted to NSF for review.

4.1.1.1 Documentation of gluten-free production practices and procedures shall include:

- product integrity;
- food contact packaging materials and storage containers;
- storage and handling of ingredients;
- cleaning and sanitation;
- ingredient and product quality control;
- training; and
- supplier approval and monitoring.

4.2 Product integrity

Gluten-free product integrity must be ensured by these methods.

4.2.1 Method for confirming gluten-free integrity of all ingredients or final products sourced.

4.2.2 Commingling and/or cross-contamination prevention of ingredients and finished product from receiving, packaging, storage and final distribution.

4.2.3 Commingling and/or cross-contamination prevention of packaging materials and storage containers.

4.2.4 Method for evaluating cross-contact and where identified, documentation regarding the installation of procedures to prevent the introduction of gluten into the manufacturing process.

4.3 Food contact packaging materials and storage containers

Information about the types and locations of food contact packaging materials and food contact storage containers used for but not limited to:

- measures in place to prevent commingling and contamination including reuse of food contact packing and bulk storage containers.

NOTE — Reuse of packaging materials is not permitted unless procedures for reusing food contact packaging materials and/or storage containers can be confirmed sanitary by an intervening step and residue testing.

— vendor assurance of food contact packaging to be free from gluten.

4.4 Storage and handling of ingredients

Certified entities must have in place policies and procedures for the handling and storage of incoming ingredients.

4.4.1 The policies and procedures shall be designed to prevent cross contamination and commingling of gluten containing and gluten-free ingredients.

4.4.2 Policies and procedures must be in place to clearly identify and segregate foods that contain gluten.

4.4.3 These documents must be included with the facility GCP, kept on file at each certified entities' facility and made available during on-site audits**.**

4.5 Cleaning and sanitation

Cleaning and sanitation method(s) and procedure(s) must be used to prevent commingling and cross-contamination including:

4.5.1 Methods to demonstrate consistent sanitation procedures.

4.5.2 Methods for evaluating the efficacy of intervening events for non-dedicated lines.

NOTE — Intervening events may include but are not limited to equipment cleaning and sanitation between non-certified and certified production.

4.5.3 The certified entities must have systems in place to identify risks associated with equipment and facility design to prevent cross-contamination and take measures to mitigate those risks.

4.5.4 Certified entities must have written validated cleaning policies and procedures in place for the sanitation of equipment used in the production of gluten-free products.

4.5.5 The policies and procedures must function to reduce cross contamination and commingling of gluten containing and gluten-free products. Cleaning and sanitation of product contact surfaces between line changeovers must be effective, appropriate to the risk and Protocol requirements, and sufficient to remove all potential gluten from product contact surfaces, including aerosols as appropriate, to prevent cross contact.

4.5.6 Documentation of sanitation procedures must be maintained and retained at the manufacturing facility for a period of not less than five (5) yr. These results must be made available during on-site audits**.**

4.5.7 These documents must be included with the facility GCP.

4.6 Ingredient and product quality control

Documentation of ingredient and product quality control procedures and testing must be maintained and retained at the production facility for a period of not less than five (5) yr. These results must be made available to NSF upon request and during on-site audits**.**

4.6.1 Ingredient(s)

4.6.1.1 A certified entity must establish internal procedures for ensuring the gluten-free integrity of their supply chain.

NOTE — Inherently gluten-free products are exempt from this requirement (e.g., raw fruits and raw vegetables that have not undergone any manufacturing, or are handled or processed only gluten-free facilities, as confirmed by NSF). Supplier affidavits may be required for processed inherently gluten-free ingredients.

4.6.1.2 Ingredients used in the production of gluten-free products shall not exceed 20 ppm.

NOTE — With the gluten-free level set by the FDA at 20 ppm, it is reasonable to assume that a certified entity could in good faith purchase "gluten-free" ingredients with a gluten level up to the 20 ppm limit. NSF has set the allowable gluten level for ingredients at 20 ppm, due to the dilution during the manufacturing process.

4.6.1.2.1 If a single ingredient is tested by a certified entity and found to have a gluten level greater than 20 ppm, they may choose to test at least 3 additional samples from the same lot (not to exceed a total of 10 samples) and take the average, dependent upon approval by NSF per the certified entity's corrective action plan. If the average gluten level is 20 ppm or less, the selected lot shall be considered to be in compliance.

4.6.1.2.2 If after testing additional samples the average gluten level is still more than 20 ppm, the certified entity shall not use the ingredient in an NSF gluten-free certified product. Documentation shall be maintained regarding the disposition of the non-compliant ingredient.

4.6.1.3 Documentation of ingredient testing shall be retained at the certified entity's facility for a period of not less than five (5) yr. These results shall be made available to NSF upon request and will be reviewed during on-site audits.

4.6.1.4 High Risk Ingredients: NSF considers the following ingredients as high risk due to their potential for cross contamination with gluten containing ingredients during harvesting or the manufacturing process:

- raw oats; and
- cereal grasses (i.e., barley grass, wheat grass).

4.6.1.4.1 If a certified entity seeks to use a high-risk ingredient in an NSF gluten-free certified product the supplier of the high risk ingredient or the certified entity must complete gluten-free testing on each lot of the incoming high-risk ingredient prior to processing. Gluten test results will be acceptable as long as the results are not more than 20 ppm.

4.6.2 Fermented and hydrolyzed foods

A certified entity shall establish internal procedures for ensuring the gluten-free integrity of fermented and hydrolyzed foods. Enzymes used as processing aids are not subject to the requirements set forth in Section 4.6.1 of this Protocol.

NOTE — There are currently not any scientifically reliable and validated testing methods to test for the presence of gluten in fermented and hydrolyzed ingredients or finished products made from wheat, rye, barley or hybrids of these grains. To certify a finished product that contains one of these ingredients, the certified entity shall demonstrate that the ingredient supplier has complied with the requirements in Section 4.6.2 and completed the NSF Gluten-Free Compliance Affidavit. Additional documentation may be requested at the discretion of NSF.

4.6.2.1 A fermented or hydrolyzed ingredient or finished product may make the NSF "gluten-free" claim only if the following criteria are fulfilled:

— Gluten containing grains are not part of the fermentation or hydrolysis process; or

— the fermentation media contains gluten containing grains. However a multi-step process is followed which consists of:

a) degradation and consumption of proteins during cell growth;

b) a purification step which includes separation of the enzymes from the media; and

c) a filtration step using microfiltration, or a smaller filtration type such as nano or ultrafiltration to remove any residual media components including gluten proteins.

4.6.2.1.3 The manufacturer appropriately and thoroughly evaluates their process for any potential for cross-contact with gluten.

4.6.2.1.4 In the event that a potential for cross-contact with gluten was to occur or was identified during risk assessment of the manufacturing process, the manufacturer shall have implemented and documented practices to prevent gluten from entering the production process. The documented practices are subject to request by NSF.

4.6.2.1.5 Certificates of Analysis may be provided as means of compliance to Section 4.8.1 by the supplier; as long as the Certificate of Analysis contains information referencing the absence of gluten and the test was conducted prior to fermentation or hydrolysis.

4.6.2.1.6 Ingredients that are tested prior to fermentation or hydrolysis and found to have a gluten level greater than 20 ppm shall be noted as a failure and are considered non-compliant. Ingredients found to be non-compliant are not permitted to be used in fermented or hydrolyzed ingredients or finished product that are labeled gluten-free.

4.6.3 Distilled Foods

4.6.3.1 Distilled ingredients or foods may make the gluten-free claim only if the following criteria are fulfilled:

4.6.3.1.1 Verification of the absence of protein in a food or ingredient using scientifically valid methods where the detected sensitivity should be zero or as close to zero as possible. Compliance to this requirement shall be demonstrated by a supplier submitted test result indicating the absence of gluten from the distilled ingredient or food.

NOTE — Testing of non-gluten containing grain prior to distillation is not required.

4.6.3.1.2 Distilled foods or ingredients that are tested and found to have detectable gluten protein present shall be noted as a failure and are considered non-compliant. Ingredients or foods found to be non-compliant are not permitted to be used in products that are labeled gluten-free.

NOTE — The FDA considers distillation as a process of removal. Therefore, should proteins be detected, the FDA concludes that protein content is a result of inadequate application of good manufacturing practices or suitability of the distillation process used.

4.6.4 Finished product(s)

4.6.4.1 A certified entity shall perform internal quality control testing on a minimum of the first unit of sellable product off each production line per lot.

4.6.4.2 A product shall not make a “gluten-free” claim if either:

— it contains an ingredient that is a gluten containing grain; or

— it contains an ingredient that is derived from a gluten containing grain that has not been processed to remove gluten.

4.6.4.3 A product may make a “gluten-free” claim if either:

— it is inherently free of gluten, provided the amount of gluten present in the finished product is no more than 15 ppm; or

— it contains an ingredient that is derived from a gluten containing grain that has been processed to remove gluten, provided the amount of gluten present in the finished product is no more than 15 ppm.

4.6.4.4 Finished products shall be found compliant if the selected product(s) are tested and have a gluten level of no more than 15 ppm.

4.6.4.4.1 Acceptable gluten testing kits for performing internal gluten testing shall be AOAC validated kits including but not limited to: AgraStrip Gluten G12 Test Kit; EZ Gluten; Aller-Tex Gluten ELISA; GlutenTox Pro; 3M Gluten Protein Rapid Kit.

4.6.4.4.2 Outside laboratories used for gluten testing shall be ISO 17025 accredited for the relevant method of testing, or approved by NSF through validation of methods or evaluation of validation study results supplied by the laboratory.

4.6.4.5 If the selected product is found to have a gluten level between 15 ppm and 20 ppm (e.g., 17 ppm) The certified entity may choose to test additional samples from the same lot (not to exceed a total of 10 samples) and take the average, dependent upon approval by NSF per the certified entity’s corrective action plan. If the average gluten level is no more than 15 ppm, the selected lot shall be considered to be in compliance.

4.6.4.5.1 If after testing additional samples the average gluten level is still between 15 ppm and 20 ppm (e.g., 17 ppm), the certified entity shall notify NSF of the failure within 48 h of receiving the test results, all finished products from the production run shall be placed on HOLD and remain in control of the certified entity, until such time they are released in writing by NSF.

NOTE — The FDA definition of gluten-free is less than 20 ppm. Given the globalization of the food supply chain and 15 ppm gluten-free limits set forth by other countries, it is possible for a certified entity to source gluten-free ingredients, and through no fault of their own, produce a test result that exceeds 15 ppm but is less than 20 ppm. In such instances, the operator shall conduct a root cause analysis to clearly indicate the source of the elevated levels of gluten and continue to closely monitor the compliance of those ingredients. This process shall be captured in the Gluten-Free Compliance Plan and as outlined in Section 4.

4.6.4.5.2 If the selected product is found to have a gluten level greater than 20 ppm, the entire lot shall be found non-compliant. The certified entity shall notify NSF of the failure within 48 h of receiving the test results, all finished products from the production run shall be placed on HOLD and remain in control of the certified entity, until such time they are released in writing by NSF.

4.6.4.6 Upon notification of a quality control failure, NSF may request that the certified entity review their GCP and conduct a root cause analysis to determine the cause of the failure. NSF may also require the certified entity to provide written corrective action to ensure the non-compliance will not occur in the future. NSF shall review both the root cause analysis and corrective action prior to issuing disposition of the product and to determine if additional testing or inspections are necessary.

4.7 Training

4.7.1 Employee gluten-free training program must be documented and implemented. Employees carrying out tasks related to the manufacture or handling of Gluten-Free products shall receive annual Gluten-Free training. At a minimum training must cover:

— sources and areas within the facility where gluten containing (ingredients or products) are located and the safe handling and cross-contamination prevention thereof; and

— basic understanding of the types and sources of gluten, where they are found, what kind of products they are in and the safe handling thereof.

4.7.2 Employee training shall be in accordance with the GCP.

4.7.3 All employee training records shall be maintained at the production facility for a period of five (5) yr and available for review during on-site audits.

4.8 Supplier approval and monitoring

4.8.1 Certified entities shall only source ingredients from vendors that ensure that no cross-contamination with gluten has occurred that could impact the compliance status of the ingredient.

Evidence of gluten-free integrity of supplied ingredients may include, but is not limited to:

— Certificate of Analysis from the supplier states a gluten level of no more than 20 ppm;

— requiring all incoming lots to be accompanied by a gluten-free test report;

— in house gluten-free testing on all incoming ingredient lots;

— Allergen Affidavits provided they reference absence of “gluten”;

— gluten-free certificate;

— supplier letters of guarantee that the ingredients purchased do not contain gluten;

— NSF Gluten-Free Compliance Affidavit;

— requiring contracts with suppliers to ensure that the Certified Entity is notified if any changes occur that may affect gluten-free compliance of the supplier material; or

— other valid measures may be approved by NSF.

NOTE — See Section 4.6.1 for ingredient testing requirements.

4.9 Audit Location

When production includes a multi-phase production process, only the final point of production shall be audited.

Facilities in the supply chain may apply for separate certification, which would require an on-site audit and assessment to the requirements of the Protocol.

4.10 Certification of trader or distributor operations

A trader or distributor that receives NSF Gluten-Free certified products that are packaged in a finished product container, prior to being received by the trader or distributor, and remain in the same package or container, without being processed or adulterated, may be granted NSF Gluten-Free certification provided documents and records meet the requirements listed under Section 4.1, as applicable, including product traceability from receipt to shipment by trader or distributor.

Additionally, requirements for disposition, complaints, and labelling per Sections 5, 6, and 7 respectively shall be met, where applicable.

4.11 Accepting other Gluten-Free certifications

4.11.1 If an organization seeking NSF gluten-free certification is certified by another certification body, NSF may accept the certificate as compliant under the following conditions:

— The gluten-free certificate states the specific product name(s) and has been issued within the previous 6 mo of starting NSF Gluten-Free certification

— The gluten-free certificate will be accepted in lieu of receiving an on-site audit by NSF for initial certification. An on-site audit will be mandatory at the annual renewal and thereafter.

— All NSF documents per 4.1.1 and 4.6.4 and their subsections will be required for completion by the organization and submitted to NSF prior to final certificate issuance.

5 Disposition plan, written withdrawal and recall procedures

5.1 In the event that a finished product fails to meet the requirements of Section 4.6.4, the certified entity shall provide notice to NSF immediately and NSF with a disposition plan for the non-compliant product. This disposition plan may include, but is not limited to:

— full destruction of the failed production run;

— the certified entity may choose to continue sale of the finished product, but shall not bear the NSF Gluten-Free Certification Mark, or the NSF Gluten-Free Certification Statement on any failed finished product, or make any generic gluten-free claims; or

— other means pre-approved by NSF.

5.2 Certified entities shall have a documented product identification system in place to ensure that product is clearly identified during all stages of production from ingredient receipt to customer.

5.2.1 Certified entities shall of a documented product trace system in place to ensure that the finished product is traceable to the customer and raw materials, including food contact packaging are traceable one step back.

5.2.2 Certified entities shall have a method for controlling non-conforming product, including recall or market withdrawal if necessary.

5.2.3 Certified entities shall have system in place for notifying their customers and other required entities when the finished product is determined to be eligible for a withdrawal or recall.

5.2.3.1 These documents shall be included with the facility GCP.

5.2.4 Certified entities must notify NSF immediately in case of withdrawal or recall of a NSF Gluten-Free Certified Product.

5.2.4.1 These documents shall be kept on file at each certified entity's facility and made available during on-site audits.

6 Complaint handling of gluten-free products

6.1 Certified entities shall have in place policies and procedures to handle and resolve complaints related to Gluten-Free compliance.

6.1.1 These documents shall be included with the facility GCP.

6.1.2 Complaints shall be kept on file for a period of five (5) yr and available during on-site audit at each certified entity's location.

7 Labeling

Use of the NSF Gluten-Free Certification Mark helps clarify the meaning of "Certified Gluten-Free" on product packaging, advertising, and promotional materials.

7.1 Labeling of certified gluten-free products shall be in accordance with these guidelines and requirements or the NSF Gluten-Free Marks Style Guide:

Figure 1 – NSF Gluten-Free Certification Marks

NSF Gluten-Free Certification Mark	NSF Gluten-Free Bilingual French-English Certification Mark	NSF Gluten-Free Bilingual Spanish-English Certification Mark

Figure 2 - NSF Gluten-Free Certification Statements

English	French	Spanish
"Certified Gluten-Free by NSF"	"Certifié Sans Gluten par NSF"	"Certificado Libre de Gluten por NSF"

7.1.1 Sanctioned use of the Mark or Statement

Sanctioned use of the Mark or statement on product packaging, labels, literature or advertising includes:

7.1.1.1 The use of the NSF Gluten-Free Certification Mark or the relevant NSF Gluten-Free Certification Statement is voluntary for use on the specific product labels which are certified gluten-free.

7.1.1.2 The Mark or statement may also be used on promotional and marketing materials for certified gluten-free products.

7.1.1.3 The NSF Gluten-Free Certification Mark is a registered trademark of NSF. No certified entity or person shall apply or use the Mark in connection with a product, or represent in any way that the product is certified, until written authorization is provided by NSF. NSF may pursue legal recourse if the mark is misused.

7.1.1.4 Any product that bears the claim “gluten-free” (or “no gluten,” “free of gluten,” or “without gluten”) in its labeling and fails to comply with the definition may be deemed to be misbranded. While NSF considers these other terms to be equivalent to “gluten-free,” NSF discourages the use of terms other than “gluten-free” in labeling so that consumers with celiac disease can look for a single term on product labels.

7.1.1.5 It may not always be feasible to use the NSF Gluten-Free Certification Mark on a product due to size or design constraints. Alternative suggestions may be submitted to NSF for approval.

7.1.2 Use of the Mark

7.1.2.1 Suggested size requirements for the NSF Gluten-Free Certification Mark at least .75 or ¾ in; must be legible.

7.1.2.2 Color options can be found in the NSF style guide

7.1.2.3 The Trademark (™) symbol must be present at the end of the word “Free” when using the NSF Gluten-Free Certification Mark in English.

7.1.3 Use of the statement

7.1.3.1 Font options: When opting to use the acceptable NSF Gluten-Free Certification Statement language, “Certified Gluten-Free by NSF,” and/or “Certifié Sans Gluten par NSF”, and/or “Certificado Libre de Gluten por NSF” in place of the NSF Gluten-Free Certification Mark, text shall be Gotham bold and legible. You may substitute Arial for Gotham if your certification project manager approves this change. If you encounter difficulty, contact NSF to discuss alternatives.

7.1.3.2 Acceptable Language: “Certified Gluten-Free by NSF” and/or “Certifié Sans Gluten par NSF” and/or “Certificado Libre de Gluten por NSF”.

NOTE 1 — The ‘C’ in “Certified” and “Certifié” and “Certificado” shall be capitalized.

NOTE 2 — Gluten-Free / gluten-free shall always contain a “dash” between gluten and free.

7.1.4 Bulk / non-retail labeling requirements

7.1.4.1 All non-retail containers, packages and labels that are used to ship or store gluten-free goods shall display a lot number that is traceable to the finished product.

7.2 Additional statements

7.2.1 References to wheat in gluten-free products

NOTE — This is for FDA regulated products only.

7.2.1.1 Some product ingredients are derived from wheat but have been modified to remove gluten (e.g., a flavoring, a modified food starch). Such products may be required to bear allergen labeling to indicate the presence of wheat, even though they bear a "gluten-free" claim. Use of the words "wheat" and "gluten-free" on the same label may confuse consumers.

7.2.1.2 If a product uses the term "wheat" in its ingredients list or in its allergen label statement (e.g., "Contains wheat"), and also bears a "gluten-free" claim (or "no gluten," "free of gluten," or "without gluten"), the food will be deemed to be misbranded unless the word "wheat" in the ingredients list or the "Contains wheat" allergen label statement is followed immediately by an asterisk (or other symbol) that refers to the following statement in close proximity to the ingredients list:

> "The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods."

7.2.1.3 Statements such as "may contain wheat" are not allowed on NSF Gluten-Free certified products.

7.2.3 Marketing outside of US and Canada

Use of the NSF statement or Mark for distribution outside the U.S. must meet these criteria.

7.2.3.1 The operation seeking certification shall note on the application forms and/or product profile forms the intended market country for each certified product.

7.2.3.2 If the intended market for distribution has a regulation for a stricter (lower ppm) action threshold (of gluten allowed in a product marketed as gluten-free) than 15 ppm, it is the responsibility of the entity seeking NSF certification to comply with the intended market country requirements.

7.2.3.2.1 Compliance with this NSF requirement does not guarantee compliance with local, state, or federal labeling regulations. The certified entity is responsible for ensuring compliance with those regulations.

8 Request for variance

Special request for variance to NSF Protocol P404 Gluten-Free may be authorized and issued at the discretion of NSF.

8.1 To apply for a variance, the client must complete the Request for Variance – NSF Protocol P404 Gluten-Free form and submit to NSF. Fees will apply as per the fee schedule for gluten-free certification services.

8.2 NSF shall consider the request but is not obligated to grant the request and will not be obligated to return any portion of fees paid if the applicant chooses to discontinue certification as a result of NSF's decision.

8.3 NSF shall not be responsible for any costs incurred by applicants related to nonconforming product which is the subject of rejected request or other product non-compliance.

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***THE HOPE OF MANKIND** rests in the ability of man to define and seek out the environment which will permit him to live with fellow creatures of the earth, in health, in peace, and in mutual respect.*