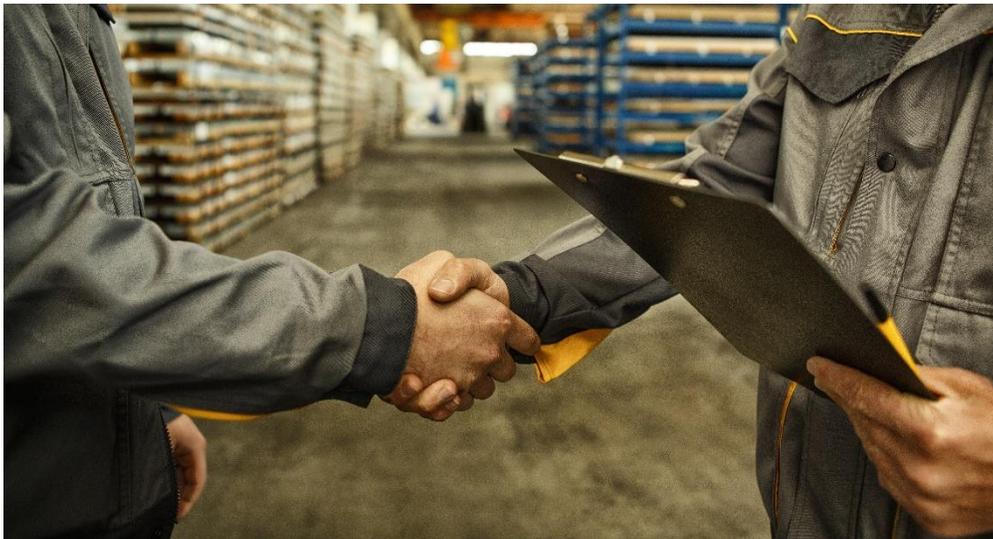


Supplier Controls Packet



Innovation Center for US Dairy
June 13, 2022 - Version A

Contents

Overview.....	1
Lexicon/Glossary of Terms.....	3
How to Avoid Making Claim Mistakes	4
Importance of Labeling for Allergen Control	10
Questionnaires: How to Gather Information and Assess Your Documents	13
Small Quantity Supply Risks: How to Protect Your Business	15
Importance of Technical Data Sheets of Common Ingredients.....	17
Overall Summary	20

Overview

Dear Cheese, Ice Cream, Dairy Manufacturer and/or Materials Suppliers:

Growing your business is very important. Yet hazards exist that can impact the food safety of products and the long-term success of your business. Whether the hazard is a microbiological organism, undeclared allergen, or foreign material, unknown hazards can put your customers' lives and/or your customers' businesses at risk. Not only are you required by the Food Safety Modernization Act (FSMA) to identify and control these hazards, but it is also your responsibility to ensure the food products you produce are safe and free from these hazards.

Sourcing materials from trusted suppliers is the best way to limit this risk. Some hazards can be controlled before they even reach your facility. Trust is built through transparency and communication with your supply chain. An important way to maintain that trust is through validation of vendors via audits which help build long-term supplier relationships. Having a trusted, validated, and diversified supply chain helps ensure product safety, reduces the frequency of supply chain disruptions, and provides traceability in the event of a recall.

This Supplier Control Food Safety Resource Packet has been created to provide a basic supplier onboarding packet with sample questionnaires, examples of Technical Data Sheets, real-world scenarios, etc. to help you better understand the importance of this documentation, which documentation is necessary, a lexicon/glossary of common terms, how to interpret the data you receive via this documentation, how to assess facility risk and inherent risk as it relates to your food safety plan, how to conduct self-audits and how to identify the key questions/conversations you should have as you approve your suppliers.

We hope you find this packet informative and easy to use as you implement your supplier control food safety plan and programs to help keep people and businesses safe and thriving.



Questions to Ask Yourself

Have you conducted a Self-Audit to identify gaps in your existing food safety plan? Are your employees trained on your food safety/supplier control program? If No, go to [Supply Chain | U.S. Dairy \(usdairy.com\)](https://www.usdairy.com) and assess your current program by filling out the Food Safety Guidance Document.

Are you making claims about your product or ingredients? Avoid common mistakes by going to [How to Avoid Common Claims Mistakes](#)

Unknown or undeclared allergens are a primary reason for costly recalls. Do you know which ingredients you use are considered allergens or may have cross-contamination with allergens? Do you know how to properly receive, label, and handle ingredients that are allergens? Do you know your product's distribution channels? Does your product go to a different country where there may be other ingredients that must be declared as an allergen? If No, go to [Importance of Labeling for Allergen Control](#)

Do you know which documents are required to keep on hand for validation and traceability in the event of an audit or recall? If not, see [Traceability Guidance Document](#), [Guide to FDA Inspections and Preparing for a Recall](#)

When you receive your questionnaire results, do you know how to assess your risks? If No, see [Questionnaires: How to Gather Information and Assess Your Documents](#), Documentation Request Form Appendix C and/or use the [DMI Risk Calculator](#)

If you use small quantities of ingredients, do you know how to validate and document them to limit your risk? Do you have a diversified list of approved suppliers in the event of a supply chain disruption or a recall? If No, go to [Small Quantity Supplies](#)

Do you know the difference between Technical Data Sheets and Safety Data Sheets (previously known as Material Safety Data Sheets) and what types of information you need to retain? If No, go to [Importance of Technical Data Sheets](#) and reference Appendix D.

Questions to Ask Your Suppliers

Have you secured documentation from your supplier from an accredited 3rd Party Auditor with a GFSI (Global Food Safety Initiative) Certification such as FSSC 22000 (Food Safety System Certification 22000), BRC (British Retail Consortium) Global Standard Certificate, or SQF (Safe Quality Food) Certification as an important first step to help addressing processing related audit concerns? If No, go to [Questionnaires: How to Gather Information and Assess Your Documents](#) and reference Appendix A & Appendix B.

Does your supplier audit review include HACCP Flow Diagram, CCP Summary/Limits, GMP Policies for control of hazards? If No, go to [Questionnaires: How to Gather Information and Assess Your Documents](#)

Unsure about the terminology of audits/questionnaires/datasheets? Go to [Lexicon/Glossary of Terms](#).

Lexicon/Glossary of Terms

Certificate of Analysis (COA) – A document issued by the supplier at the request of the receiving site (purchaser) which contains analytical test results for critical raw material/packaging material specification parameters.

Critical Control Points (CCPs) – Steps at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Distributor – An intermediary entity between the producer of a product and another entity in the distribution channel or supply chain, such as a retailer or a value-added reseller.

Flow Diagram – A diagram of the sequence of movements or actions of people or things involved in a complex system or activity.

Food Safety Plan – A set of written documents that shows how a food business operates safely during manufacturing, processing, packing, and holding. It is a requirement for almost all food producers under FDA regulation.

Global Food Safety Initiative (GFSI) – A coalition of retailers and manufacturers that helps oversee food safety standards for businesses and provides access to safe food for people everywhere through the accreditation of certified 3rd party auditors.

Good Manufacturing Practices (GMPs) – Good Manufacturing Practices (GMPs) have two meanings when used in the context of a food processing facility. First, it refers to actual federal code sections that provide the regulation for both federal and state food processing regulations that serve to cover facility construction, equipment and utensil selection, sanitization, personnel hygiene, food handling, and production and processing controls.

The second definition refers to a set of operating procedures and practices that are required to confirm the guidelines recommended by agencies that control the authorization and licensing for the manufacture and sale of food, drug products, and active pharmaceutical products. These are the minimum requirements that a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or the public.

Hazard Analysis and Risk-Based Preventive Controls (HARPC) – The requirements are similar to the Hazard Analysis and Critical Control Point (HACCP) requirements which identify hazards that might arise due to the specific foods or food ingredients in the food or due to the various processing, manufacturing, packing, and holding steps applied to the foods. HARPC does not distinguish CCPs from other types of Preventive Controls.

Hazard Analysis Critical Control Points (HACCP) – A system that identifies, evaluates, and controls hazards that are significant for food safety. HACCP identifies Critical Control Points but does not recognize Preventive Controls. HACCP is the internationally accepted, science-based system for ensuring food safety controls, harmonized with the current recommendations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

Labeling Requirements – FDA’s publication, “[A Food Labeling Guide](#)” that includes information on basic food labeling as well as information on nutrition facts, trans fat, and allergen labeling. Labeling not only is a marketing tool, but it informs the consumer of what they are purchasing. Ingredients of the food, composition (including trans fats, caloric values, and other nutritional information), allergens, panel requirements, and placement, company information, and much more are addressed by the Code of Federal Regulations. The full labeling requirements may be found at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide>

Preventive Controls (PCs) – Reasonable and appropriate procedures, practices, and processes that a person knowledgeable about the safety of food would employ to significantly minimize or prevent hazards.

Supply-Chain Preventive Control – means a preventive control for a hazard in raw material or other ingredients when the hazard in the raw material or other ingredient is controlled before its receipt.

How to Avoid Making Claim Mistakes

Marketing your products and building your brand is a large part of growing your business. You have a great product, and you want to tell everyone about it. Be careful that you are not making any invalid claims that could inadvertently damage your brand. Using trending buzzwords to grab your customers’ attention is an easy way to make a claim mistake whether you know you are doing it or not. There are rules and regulations regarding identity-preserved products. Consumers rely on these claims to make their buying decisions, and producers need to be able to have evidence to support these claims. Understanding what it means to have a Kosher certified, non-fat, organic cheddar cheese is very important. There are specific labeling requirements by FDA, USDA, FTC, and other organizations that are just as critical to your brand. Lawsuits happen frequently and it is always best to consult with legal experts to ensure compliance prior to making claims.

Organic – Organic products follow standards that are regulated by the National Organic Program, a federal regulatory program within the United States Department of Agriculture (USDA). There are specific requirements that allow farms and businesses to label their food with an organic seal or even just the word “Organic.” The 4 categories that fall under the organic standards are Crops, Livestock, Processed Products, and Wild Crops.

Like other 3rd Party Audits, there is an organization that creates the rules (USDA) and then there are other organizations that have programs to fulfill these rules. Those organizations are called certifiers. The USDA approves these certifiers to audit farms and businesses annually to allow them to claim their products are organic. There are over 80 certifiers, and each one has its way of certifying products. The Organic Integrity Database has a Certifier Locator (<https://organic.ams.usda.gov/Integrity/Certifiers/CertifiersLocationsSearchPage.aspx>) to help find a certifier based on region. If there are multiple agents available, learn about their programs to see which one best fits your company.

There are 4 different levels of organic certification based on the percentage of organic ingredients within the finished product. From highest to lowest, they are 100% Organic, Organic, Made with Organic, and Organic Ingredients.

100% Organic	Organic	Made with Organic	Organic Ingredients
✓ Organic seal allowed	✓ Organic seal allowed	✗ Organic seal NOT allowed, Must specify which ingredients are organic	✗ Organic seal NOT allowed, Product can't be described as "organic"
✓ 100% certified organic ingredients and processing aids	✓ 95 % certified organic ingredients	✓ At least 70% certified organic ingredients	✗ No specific % certified organic
✓ No GMOs	✓ No GMOs	✓ No GMOs	✗ May contain GMOs
✓ All ingredients comply with National List of Allowed and Prohibited Substances	✓ Non-organic ingredients comply with National List	✓ Non-organic ingredients comply with National List	✗ Compliance with National List not required
✓ Certification required	✓ Certification required	✓ Certification required	✗ Certification NOT required

Learn more about organic labels at www.ams.usda.gov/organic

Agricultural Marketing Service, April 2018
USDA is an equal opportunity provider, employer, and lender.

Not Bioengineered – Bioengineered foods are defined in the USDA by the 2016 National Bioengineered Food Disclosure Law as food (a) that contains genetic material that has been modified through in vitro recombinant DNA techniques; and (b) for which the modification could not otherwise be obtained through conventional breeding or found in nature. United States Department of Agriculture (USDA) (Agriculture Marketing Service) is in the process of developing a national mandatory system for disclosing the presence of bioengineered ingredients, in order to provide desired information to consumers.

This law is not being put in place for safety reasons, as there is no evidence of meaningful differences between genetically engineered foods and their non-genetically engineered comparison foods in terms of safety, however, each food is considered individually. The Proposed Rule to implement the National Bioengineered Food Disclosure Standard was published in the May 4th Federal Register with a suggested compliance date of January 1, 2020. Any food that is certified organic will not be required to disclose the genetically engineered ingredient content.

Foods derived from animals that consumed feed containing bioengineered substances are not considered bioengineered because of the feed. Dairy products including milk and cheeses from animals that have consumed GMO feed will not be subject to labeling requirements because of the feed.

Items and/or ingredients to consider:

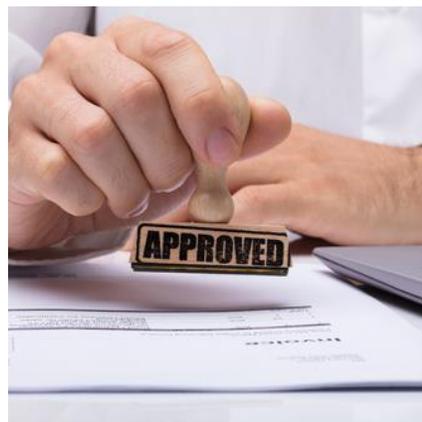
- Cultures
- Enzymes
- Flavor additions
- Flow agents

Natural – First off, a common misconception is that if a product is “Organic” it is “Natural.” Although a product can be both considered “natural” and “organic,” it does not mean that all organic products are natural, or that all natural products are organic.

The FDA regulations are silent on when manufacturers can label a food “Natural,” but FDA has provided some guidance on the use of such terms. The FDA’s stance is that any ingredient of artificial origin or any added color such as annatto and beta carotene (even if they are naturally derived) would not be allowed in products labeled “Natural.” Natural claims are also frequently the target of class action litigation as lawyers seek to capitalize on the lack of FDA regulation and consumer variations of what is, and is not, “natural.” Some of the more common targets of litigation include using starches to prevent caking, ingredients subject to more than minimal processing, and trace amounts of genetically modified foods or pesticides. Relatedly, the term “natural” has been an item of debate for products with some ingredients derived from bioengineered materials. Please see the below link from the Federal Register on this topic (first link below).

All manufacturers must comply with the new National Bioengineered Food Disclosure Act standard (BE Rule) applicable to all foods. For cheese, the standard has been controversial because many enzyme inputs (such as corn oil) and even the production organism itself, may be derived from bioengineered crops or be bioengineered. Although fermentation inputs are typically “incidental additives” under FDA regulations, USDA’s Agriculture Marketing Service’s (AMS) staff caused confusion within the industry over labeling obligations for enzymes. Fortunately, in late 2021, USDA dispelled any confusion and confirmed that any fermentation inputs that meet the FDA’s definition of “incidental additives” not declared in the ingredient list are exempt from disclosure under the BE Rule. This means that in most cases, cheese enzymes will not trigger a BE disclosure requirement. USDA further noted that enzyme manufacturers and cheese companies are in the best position to make that determination and maintain customary business records on incidental additives.

There are two phases of the question “Is the product Natural”: Does this pass FDA expectations? And will you have lawsuits and litigation from consumers? If the cheeses do not contain annatto or beta carotene and they contain only salt and pasteurized milk and cultures, there have not been significant regulatory concerns about these products making a “natural” claim. I would make sure your firm has the proper documentation from your suppliers about the bioengineering status of any ingredients used that may be bioengineered or sourced from crops on the AMS BE Food List. That said, it is very difficult to predict whether a product label will result in litigation, as “natural” claims are common targets for litigation. Your company’s in-house counsel and lawyers specializing in defending against labeling claims are in the best position to help your company navigate labels and lower the risk of litigation.



Below are links to the FDA’s current thoughts on this matter.

[Federal Register: Use of the Term “Natural” in the Labeling of Human Food Products; Request for Information and Comments](#)

[Use of the Term Natural on Food Labeling | FDA](#)

Reduced Fat, Low Fat, or Non-fat – For the purpose of nutrition labeling (e.g., the Nutrition Facts) and making product claims, nutrient amounts are declared for one serving of the food based on a pre-determined quantity of food set by FDA regulations. The “Serving size” labeled on the Nutrition Facts is based on a standardized Reference Amount Customarily Consumed (RACC) for that food category. To define a RACC, the FDA used national food consumption survey data of Americans four years and older. RACCs are not recommended serving sizes, but rather by law, RACCs must be based on how much food people actually consume. The regulations for RACCs were updated at the same time the nutrient regulations were updated on May 27, 2016. The quantities for some but not all food categories were adjusted to represent the latest survey data. See [Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category: \(fda.gov\)](https://www.fda.gov/oc/ohrt/guidance-for-industry-reference-amounts-customarily-consumed-list-of-products-for-each-product-category)

A relative nutrient content claim is one that describes the level of a nutrient in one food compared to the level in another food, such as 50% less fat than regular cheese. Descriptor terms that are defined by regulation and frequently used as relative claims are light, lite, reduced, less, or more. In light and reduced claims, the comparison must be for similar foods; for example, reduced-fat Swiss cheese would be compared with regular Swiss cheese, or lite cream cheese with regular cream cheese. Additionally, for a light claim, the reference food can only be the marketplace norm or from a national nutrient database for that food and cannot be from a single product, such as a company’s regular product. Monitor the marketplace yearly to ensure that reference (comparison) products are still in commerce across a region or nationally.

More and Less Claims: The comparison may be between either similar foods or dissimilar foods within the same product category (e.g., potato chips and pretzels are dissimilar foods but are both snacks). The nutrient levels used for the reference or comparison foods may come from a valid database, an average of the top three brands, a market leader, a manufacturer’s regular product, or a competitor’s product

The following two comparative statements must accompany all relative claims:

- Identity of the reference food and the percentage (or fraction) of nutrient difference between the product and the reference food (e.g., 50% less fat than [reference food], or 1/3 fewer calories than [reference food]) must appear on the principal display panel adjacent to the relative claim.
- Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that in the reference food may appear on either the principal display panel or the information panel (e.g., fat content has been reduced from ___ g to ___ g per serving). Include the household measurement or metric weight of the serving to avoid misleading representations

Reduced Claims: Dairy products can be modified to reduce the number of certain components such as total fat, saturated fat, sodium, cholesterol, total sugar,³⁶ or calories to meet consumer needs and preferences. This can provide a marketing opportunity for reduced claims. FDA regulations provide certain descriptors such as free, reduced, and low (very low is for sodium only) for nutrient content claims to describe the nutritionally modified product. Calories, Total Fat, Saturated Fat, Cholesterol, Sodium, and Sugar all have their own definitions and criteria that must be met in order to use these terms. In general, to use a reduced claim, there must be at least a 25% reduction per RACC for the nutrient. Less and lower may be used as synonyms for reduced. When making a reduced nutrient content claim about calories, fewer may be used as a synonym instead of less. Reduced claims are required to be accompanied by the same comparative information as other relative claims. For example, a lower fat Swiss cheese might label as

Reduced Fat Swiss Cheese. 37% less fat than our regular Swiss Cheese. Reduced Fat Swiss 5g fat per serving, regular Swiss cheese 8g fat per serving.

[See DMI Quick Reference Guide Nutrition Claims for Dairy Products 2018.pdf.pdf \(usdairy.com\)](#)

CLAIM*	NUTRIENT DESCRIPTORS AND SYNONYMS	FDA DEFINITIONS AND CRITERIA	REQUIRED STATE-MENTS ^b	EXAMPLES OF ELIGIBLE DAIRY PRODUCTS
<i>Fat-free</i> ¹⁵¹	<ul style="list-style-type: none"> • <i>Free of fat</i> • <i>Fat-free</i> • <i>No fat</i> • <i>Negligible source of fat</i> • <i>Zero fat</i> • <i>Without fat</i> • <i>Skim (milk only)</i> 	Less than 0.5 g total fat per RACC and per labeled serving size. No added fat (unless the food contains any ingredient that is a fat or that would be understood by consumers to contain fat, then the name of that ingredient in the label's ingredient list must have an asterisk (*) referring to a footnote such as <i>"Adds a trivial amount of fat"</i> . Food must be processed to achieve fat-free composition (otherwise the product is a "fat-free food").	1, 3	<ul style="list-style-type: none"> • Fat-free milk • Fat-free yogurt • Fat free cheese
<i>Low-fat</i> ¹⁵²	<ul style="list-style-type: none"> • <i>Low in fat</i> • <i>Low source of fat</i> • <i>Little fat</i> • <i>Contains a small amount of fat</i> 	<p>Maximum of 3 g total fat per RACC (when RACC is greater than 30 g or 2 tbsp).</p> <p>Maximum of 3 g total fat per RACC. (Additionally, when RACC is 30g or less, or \leq 2 tbsp, it has to meet these requirements per 50 g of food). Food must be processed to achieve low-fat composition (otherwise claim is, "product, a low-fat food").</p>	1, 3	<ul style="list-style-type: none"> • Low-fat (white and flavored) milk (1% milk fat) • Low-fat (plain and flavored) yogurt • Low-fat cottage cheese (1% and 2% milk fat) • Orange sherbet
<i>Reduced-fat</i> ¹⁵³	<ul style="list-style-type: none"> • <i>Reduced in fat</i> • <i>Fat reduced</i> • <i>Less fat</i> • <i>Lower fat</i> • <i>Lower in fat</i> 	<p>At least a 25% reduction in total fat per RACC in comparison to an appropriate reference food.¹⁵⁴ Claim cannot be made if reference (comparison) food meets definition for <i>low-fat</i>.</p> <p>NOTE that a <i>reduced claim</i> is a <i>relative nutrient content claim</i>. See statement requirements in this table footnote.</p>	1, 2	<ul style="list-style-type: none"> • Reduced-fat milk (plain and flavored) 2% milk fat) • Low-fat Greek yogurt (plain and flavored) • Light ice cream • Many of the <i>reduced-fat</i> and <i>light</i> cheeses, butters and other dairy products

Gluten-Free – In addition to limiting the unavoidable presence of gluten to less than 20 ppm, FDA allows manufacturers to label a food “gluten-free” if the food does not contain any of the following:

- an ingredient that is any type of wheat, rye, barley, or crossbreeds of these grains,
- an ingredient derived from these grains and that has not been processed to remove gluten, or
- an ingredient derived from these grains that have been processed to remove gluten, if it results in the food containing 20 or more parts per million (ppm) gluten

Foods that are inherently gluten-free, for example, bottled spring water, fruits and vegetables, and eggs can also be labeled “gluten-free” provided any gluten that came in contact with the food is less than 20 ppm.

A food label that bears the claim “gluten-free,” as well as the claims “free of gluten,” “without gluten,” and “no gluten,” but fails to meet the FDA requirements for use of these terms is considered misbranded and subject to regulatory action by FDA.

There are no valid tests to detect gluten in foods that are hydrolyzed and fermented, like cheese and yogurt. So, if they display a gluten-free claim, manufacturers must keep certain records to show that the foods meet "gluten-free" standards.

If you have any doubts about a product's ingredients and whether or not the product is gluten-free, the FDA recommends that you should contact the manufacturer.

Verified GMO-Free – The term “Not Bioengineered” and Verified GMO (Genetically Modified Organism) Free are in very similar categories, but one is the USDA regulatory expectation for labeling “Not Bioengineered”, whereas Verified GMO-Free is a specific certification that can be achieved through *The Non-GMO Project website*. This process is an audit of your documentation for each of your ingredients that you have verified that is free from Genetically Modified Organisms. Suppliers of your ingredients will need to give your firm proof that the material is indeed GMO-free.

This certification not only verifies this documentation, but it verifies that you can properly mock trace these products and check other quality systems. Here is the link to the Non-GMO standard [Non-GMO-Project-Standard-Version-16.pdf \(nongmoproject.org\)](https://www.nongmoproject.org/non-gmo-project-standard-version-16.pdf)



Lactose-Free – Although the Food and Drug Administration (FDA) has definitions for free nutrient content claims for some nutrients (e.g., fat-free), there is no regulatory definition for lactose-free.

On FDA's website for consumers, they state, “There is no FDA definition for the terms “lactose-free” or “lactose-reduced,” but manufacturers must provide on their food labels information that is truthful and not misleading. This means a lactose-free product should not contain any lactose, and a lactose-reduced product should be one with a meaningful reduction. Therefore, the terms lactose-free and lactose-reduced have different meanings, and a lactose-reduced product may still contain lactose that could cause symptoms.” The agency also has indicated in a 1993 response to a request for labeling regulations that manufacturers may voluntarily label food as lactose-free, provided that the statement is true, noting that any product labeled as lactose-free must not contain lactose as an ingredient or as a component of an ingredient and should adhere to the provisions of 21 CFR 105.62 on hypoallergenic foods.

The regulation for hypoallergenic foods indicates that the label should include an informative statement of “the nature and effect of any treatment or processing of the food... if the changed allergenic property results from such treatment/processing.” Dairy food labels with lactose-free claims, thus, would be expected to bear a statement describing how they were processed to become lactose-free.

Claim Mistakes Summary

Claims typically require more work to produce the evidence needed. Some claims require documentation while others physically change your business processes. Make sure to consider the pros and cons of each claim. The return needs to be able to outweigh the increase in potential labor and other operating costs.

Importance of Labeling for Allergen Control

Allergens are responsible for the majority of recalls in the United States. Allergens cause between 33% and 50% of all recalls. The FDA currently recognizes 8 allergens and considers them the “Big 8 Allergens.” These are believed to cause 90% percent of all allergic reactions. The “Big 8 Allergens” are milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. Effective January 1, 2023, Sesame will be added as the 9th allergen recognized by FDA. Allergens are acceptable to have in your final product, as long as they are declared on the label. In regard to Allergens in supply chain management, there are 2 key areas:

Allergen Labeling

Allergen Policy and Sanitation



Eight foods are identified as major food allergens. Under the FASTER Act of 2021, sesame is being added as the 9th major food allergen effective January 1, 2023.

<https://www.fda.gov/food/food-labeling-nutrition/food-allergies>

Supplier Allergen Labeling:

The supply chain is the first line of defense for any materials entering the building. For your supply chain preventive controls, it is important you control what materials come in through an approved supplier program that requests various documentation laid out in the supplier questionnaire template. For your supply chain receiving procedure, you should be reviewing the Certificate of Analysis, as well as the incoming material labels for allergen declarations. If there is an ingredient or material that arrives at the facility with an allergen declaration/label that is different than what the supplier stated in specifications or what is allowed in your facility under your firm's allergen policy, it should be placed on hold and the disposition should be determined. All allergens should be labeled on incoming packaging of ingredients and materials.

Allergen Control Policies

Each approved ingredient and packaging supplier should have an allergen policy that will include

- Storage Procedures
 - Storing like above like allergens or not storing materials of differing allergens touching one another.
- Allergen procedures and policies that include direction on
 - Employee PPE (i.e.. Temporary smocks, designated smocks, etc.)
 - Equipment/Line Allergen Designation or Scheduling practices
 - Designated/color coding tools and utensils
 - Wheeled cart and vehicle procedures (i.e.. Forklift room designation)
 - Lubricant evaluation
 - Receiving procedures
 - Labeling Procedures
 - Break Room and Locker Room Expectation (i.e.. Are loose nut candy bars allowed in vending machines or allowing lunches with allergens?)
 - Standard Sanitation Operating Procedures and cleaning validation program
 - i.e.. Do they depend on visual inspection? Allergen swabs? Total Protein swabs to determine allergens are removed?
 - If the product is run on the same line as allergens not permitted in your facility, request an allergen cleaning validation. *This is not required by law (FSMA) but is a Best Practice.*
 - Allergen Analysis per product supplier
 - This should describe if:
 - ✓ Allergens exist in the product
 - ✓ The product is manufactured on the same line as other allergens
 - ✓ The product is produced in a facility that makes other allergens

If you have any materials received where you question if there may be an allergen, such as Cultures (using soy media), Nuts, Walnut Wood Chips (Smoking), Beer (Rind washes or other flavors), Coconut Oil – request a statement from the supplier on whether their materials are considered to carry one of the 8 major allergens or if their manufacturing process removes an allergen.

Policies to consider:

Non-conformance notification process – *Who, how, and when should a supplier notify you of materials/processes not meeting specifications*

Change Control – *Who, how, and when should a supplier notify you of changes within their process/facility which could impact food safety (i.e., introduction of a new allergen)*

EXAMPLE: Grate Creamery is looking to try a black pepper spice from a different supplier, Company B. Having a proper supplier assessment to evaluate Company B, they identify that Company B processes an allergen, tree nuts, in their facility. Tree nuts are not currently an allergen present in Grate Creamery's plant.

Things to consider:

1. Does Company B have documents detailing preventive controls in place to prevent cross-contamination? An Allergen Summary or Full Policy will usually outline what preventive controls are in place. FDA does not require or recommend 'may contain' statements and prefer that manufacturers instead use validated preventive controls and accurate contains statements.
2. If they do not have a documented policy, can the ingredient be tested for the tree nut allergen?



Questionnaires: How to Gather Information and Assess Your Documents

Supplier questionnaires and documentation requests are meant to be tools to better understand the environment and processes that surround the products you are purchasing. Some parts of these documents are standard for every supplier while other parts will be specific to the product you are purchasing or the final product you are making. You, as the final food product producer, have the right and responsibility to determine what information is needed to produce safe food.

Through your Food Safety Plan, you have identified certain hazards that may be introduced into your process. Questionnaires and documentation requests are a way to understand if these hazards are being controlled before they arrive at your facility or if you need to add or change a step to your process to control these hazards.

These requests are also a way for you to build trust with your supplier. Suppliers should be transparent with their food safety practices, and they should be held accountable to do what they said they are doing. It is not always feasible to visit every supplier. Approach assessment of supplier as 1. What is the history of the supplier/what has been the performance? 2. What is their current state? 3. How do you expect them to perform and what is needed to know if there is a change? Conducting a Supplier Risk Analysis will help to justify which suppliers to visit in person versus a virtual or paper audit.



Documentation Requests are just as they sound. They are requests for statements, certificates, or information regarding either the facility or product. Some documents can be marked as required meaning the supplier must provide something on that topic. These are typically food safety-related documents: HACCP Flow Diagram, 3rd Party Audit Certificate, Ingredient Specification, etc. Other documents may be considered Supplemental Documents and the request may not apply to all products, such as Organic Certification, rBST Statement, Non-GMO Project Compliance, etc. These document priorities are dependent upon what you deem as necessary for your final product. If you are producing an organic certified final product, the Organic Certification request will be considered a required document instead of a Supplemental Document.

A Questionnaire focuses on facility policies and processes. If the supplier does not hold a GFSI (Global Food Safety Initiative) Certification or if your Supplier Risk Analysis warranted further details of a process or facility, a Supplier Questionnaire will help to fill in those gaps. It will typically ask specific questions about Good Manufacturing Practices (GMP), Allergen Management, Sanitation Controls, and other food safety-related processes. It is important to understand what applies to which supplier. You may have multiple questionnaires based on the type of supplier. For instance, if you are purchasing primary packaging maybe an Allergen Management program is not required because there are no allergen hazards. That same primary packaging company may also sell equipment that needs a lot of chemical lubricants. A Chemical Control policy may be needed to ensure there is not cross-contamination. The best practice is to lay out your questionnaires based on the type of supplier. Then signify the questions that are mandatory for that supplier type. When you get your questionnaires back, it will be easy to see if the required questions have been completed to your satisfaction.

Questionnaires do take longer to complete than the Document Requests. Some larger suppliers that get questionnaire requests regularly may not complete your questionnaire. They may send a document that highlights their programs. If that happens, review that document to see if it answers the required questions. If something is signified as required, but the question has not been answered, then a further discussion with that supplier may be necessary.

EXAMPLE: Grate Creamery currently purchases packaging film from film Company A. Grate Creamery emphasizes their change control process expectations and communication channels. When Company A completes the installation of a new water system, they now can switch between water sources from city municipality water or a water reservoir adjacent to their plant. Because there are clear expectations on what changes Grate Creamery is needing to be notified of, they can perform a risk analysis before Company A switches water sources. Microbiological assessments should be reviewed and evaluated for food safety and quality impact.

Things to consider:

1. Although change control process expectations have been communicated with Company A, that does not always mean Company A is communicating the changes. Company A might not understand how a certain change affects each customer. It is important to routinely ask for information that is crucial to your process. Then evaluate the changes that may have occurred because ultimately you are responsible for the end product.

Small Quantity Supply Risks: How to Protect Your Business

Considerations for procuring an in-market ingredient from an alternate source, such as a retail establishment, cottage food producer, or farmers' market, because of lack of a known supplier or purchasing power.

1. General Considerations:

- Alternate ingredients may not be held to the same food safety standards as “standard” ingredients.
- It will generally be harder to obtain food safety documentation from an alternate ingredient manufacturer.
- If possible, a distributor is a better option because more thorough food safety documentation will generally be available. Distributors can be a solution for purchasing small amounts of ingredients.
- Traceability can be managed from lot code information on a packaged product, but lack of traceability is an issue for non-packaged goods (e.g., bulk products at a grocery store, products from a farmers' market).
- The buyer should be aware of applicable regulations for the product purchased and should prioritize products with greater regulatory oversight (e.g., FDA Food Code, State Cottage Food Laws).
- Purchasing shelf-stable products will generally be a lower risk compared to refrigerated/frozen products because of a lack of visibility to supply chain temperature control.
- The product must be used as instructed (e.g., heating instructions, storage temperatures) and as designed to not introduce hazards. For example, a dry granola product may be safe as purchased because of low water activity, but if it is added to a higher moisture product microbial growth could occur.
- Having multiple verified suppliers is important for business continuity. Acts of nature and supply-chain delays can disrupt your business if you do not already have alternative sources identified. When disruptions occur time is of the essence. Having these suppliers in place ahead of time will save you time when you most need it and ensure the safety of your finished product.

2. Considerations for Retail Purchases:

- Many retailers may not have food safety programs in place. Larger retailers are more likely to have programs in place, and will potentially be GFSI certified (e.g., SQF has a retail guidance document), and therefore, if possible, these types of retailers should be prioritized.
- Consider reaching out to the product manufacturer for food safety information.
- Consider requesting information from the retailer, such as:
 - Pest control
 - Food defense
 - Temperature control
 - Employee training / sanitary practices
 - Tamper prevention
- Consider investigating the product manufacturer with compliance software (e.g., TraceGains, ReposiTrak).



- These companies provide data collection and dissemination services. They offer an interface between the producer and the ingredient supplier or finished product customer to share the necessary qualification documents. The services work differently, but typically they include document search functions and reporting tools. The goal of these services is to streamline the sharing of documents, therefore saving time and resources. Clients may not find this to be the case, however, especially as they learn the system. For example, the data service companies may have unique data formats and requirements, which may not conform with what is used by the client, forcing the need for document editing. Also, there have been complaints about repetitive information having to be entered. Finally, it is important to note that there will most likely be a cost associated with the service for the producer and/or ingredient supplier and finished product customer.

Potential Advantages:	Potential Disadvantages:
<ul style="list-style-type: none"> • Documents are kept in an online repository for ease of searching and collection • An account representative may lead the communication between the producer and supplier and/or customer • The interface allows searching for an item or supplier by name or number, and documents by type or expiration date • Creation of unique system dashboard views, admin rights, and workflows for different roles • Generation of reports from data you choose • Tracking of the percent of documents received • Communication with ERP and procurement systems 	<ul style="list-style-type: none"> • Document uploading can take time and resources • Implementation, including encouraging all parties to use the system, can be challenging • All parties may not agree to take on the cost of a program

Importance of Technical Data Sheets of Common Ingredients

Technical Data Sheet (TDS) is a great resource for any ingredient, chemical, or primary packaging material that is used within a facility. This document sets the expectations to ensure that the product is consistent and meets requirements. It is an agreement for both the supplier and the buyer. Based on the information provided in the TDS, the buyer is agreeing that this is the exact product they desire, and the supplier is agreeing that this is the product they will supply. Technical Data Sheets (TDS) differ from Safety Data Sheets (SDS). SDS documents contain information on the potential health effects of exposure to chemicals and safe working procedures when handling chemical products. It contains hazard evaluations on the use, storage, handling, and emergency procedures related to that material. SDS documents are required to be on file by the Occupational Safety and Health Administration (OSHA) to help protect employee health.



Technical Data Sheets (TDS) on the other hand are created by the suppliers and come in many formats with different names. Technical Information, Product Data Sheet, Product Description Sheet, Product Specification, or Product Information are all examples of other names that could be used. It is important to know what information you are expecting to ensure you are getting a document that contains the information you need. A best practice is to retain the document for a period based on the shelf-life of the finished good that the ingredient is used in. As a customer, you

may be able to request a specific specification sheet that is a customized version of the supplier's general TDS or provides further information that meets your specific product requirements (e.g., microbiological specifications).

The supplier is the manufacturer or grower of the product. The document should have the supplier's business name and address identified. The product name, item code, and revision date should also be included. It is important to note that most suppliers do not update their TDS if there has been no change. If the date provided on the TDS is older that does not always mean that the document is outdated. It may just mean there has not been a change to that product. With that being said, it is still best practice to request the current TDS each year to ensure that no changes have been made. Then document the date the TDS was reviewed to have on record that the document was current as of that date.

Ingredient Declaration/Composition – This section should state what makes the ingredient. If it is a natural ingredient it may just be one item, like citric acid. Other items such as cultures will include the specific bacteria species. Cultures may also contain other items that have been used as carriers or processing aids. Carriers are substances that have been added to a product for a specific purpose (to dilute, disperse, etc.) and are present in the final product. While processing aids may not be noted because they are not present or provide functionality in the finished

product. If processing aids are a concern, you may need to request additional information from the manufacturer in the form of a specific statement.

Intended Use/Application – This section will include how the product is supposed to be used. If there are any specific temperatures or dosage levels, they will be stated here. These are typically guidelines that can be altered per recipe. It is important to know how the product was meant to be used, because if it is used in other methods that might require further risk analysis to be performed.

Characteristics – There are 3 types of characteristics in products: Physical, Chemical, and Microbiological. The physical characteristics will include color, odor, size, flavor, or appearance. If there is something special with the product like a natural separation or extraneous materials that could be present, it should be stated here.

The chemical characteristics will include the pH, specific gravity, or salt content depending on what is important for a specific product.

The microbiological characteristics will include organisms of interest that could be present in the ingredient or it is an area of concern that you want to make sure does not show up in your final product. This is a way of stating what specifications of that organism are acceptable in this ingredient. There are specific standard values that are established, and each manufacturing batch of the ingredient will pass these specifications.

A Certificate of Analysis (COA) is a document that shows the results of the tests for the organisms stated in the microbiological characteristics. This document may also contain results for the physical and chemical characteristics as well.

<p>From Technical Data Sheet:</p> <table border="1"> <thead> <tr> <th colspan="2">MICROBIOLOGICAL SPECIFICATIONS</th> </tr> </thead> <tbody> <tr> <td colspan="2">Microbiological quality control - standard values and methods</td> </tr> <tr> <td>Non Lactic Acid Bacteria</td> <td>< 500 CFU/g</td> </tr> <tr> <td>Enterobacteriaceae</td> <td><10 CFU/g</td> </tr> <tr> <td>Yeasts and Molds</td> <td><10 CFU/g</td> </tr> <tr> <td>Enterococci</td> <td><100 CFU/g</td> </tr> <tr> <td>Coagulase-positive staphylococci</td> <td><10 CFU/g</td> </tr> <tr> <td>Salmonella spp.</td> <td>neg./25g</td> </tr> <tr> <td>Listeria monocytogenes</td> <td>neg./25g</td> </tr> <tr> <td colspan="2">Analytical methods available upon request</td> </tr> </tbody> </table>	MICROBIOLOGICAL SPECIFICATIONS		Microbiological quality control - standard values and methods		Non Lactic Acid Bacteria	< 500 CFU/g	Enterobacteriaceae	<10 CFU/g	Yeasts and Molds	<10 CFU/g	Enterococci	<100 CFU/g	Coagulase-positive staphylococci	<10 CFU/g	Salmonella spp.	neg./25g	Listeria monocytogenes	neg./25g	Analytical methods available upon request		<p>From Certificate of Analysis:</p> <table border="1"> <thead> <tr> <th>Characteristic</th> <th>Result</th> </tr> </thead> <tbody> <tr> <td>Non-lactic acid bacteria (CFU/g)</td> <td>< 500</td> </tr> <tr> <td>Enterobacteriaceae (CFU/g)</td> <td>< 10</td> </tr> <tr> <td>Yeasts and mold (CFU/g)</td> <td>< 10</td> </tr> <tr> <td>Enterococci (CFU/g)</td> <td>< 100</td> </tr> <tr> <td>Coagulase-positive Staphylococci (CFU/g)</td> <td>< 10</td> </tr> <tr> <td>Salmonella (CFU/25g)</td> <td>absent</td> </tr> <tr> <td>Listeria monocytogenes (CFU/25g)</td> <td>absent</td> </tr> </tbody> </table>	Characteristic	Result	Non-lactic acid bacteria (CFU/g)	< 500	Enterobacteriaceae (CFU/g)	< 10	Yeasts and mold (CFU/g)	< 10	Enterococci (CFU/g)	< 100	Coagulase-positive Staphylococci (CFU/g)	< 10	Salmonella (CFU/25g)	absent	Listeria monocytogenes (CFU/25g)	absent
MICROBIOLOGICAL SPECIFICATIONS																																					
Microbiological quality control - standard values and methods																																					
Non Lactic Acid Bacteria	< 500 CFU/g																																				
Enterobacteriaceae	<10 CFU/g																																				
Yeasts and Molds	<10 CFU/g																																				
Enterococci	<100 CFU/g																																				
Coagulase-positive staphylococci	<10 CFU/g																																				
Salmonella spp.	neg./25g																																				
Listeria monocytogenes	neg./25g																																				
Analytical methods available upon request																																					
Characteristic	Result																																				
Non-lactic acid bacteria (CFU/g)	< 500																																				
Enterobacteriaceae (CFU/g)	< 10																																				
Yeasts and mold (CFU/g)	< 10																																				
Enterococci (CFU/g)	< 100																																				
Coagulase-positive Staphylococci (CFU/g)	< 10																																				
Salmonella (CFU/25g)	absent																																				
Listeria monocytogenes (CFU/25g)	absent																																				

Packaging – This section states how the ingredient should be presented to you. Whether it is in a foil packet, a bag, an HDPE container, etc. it should be consistently in the same package. This will help with identifying potential food fraud or tampering. Also, the packaging of the ingredient is important to understand if any indirect food additives could be getting into your final product. The packaging should be a food-grade container.

Storage – Proper storage of ingredients is important for food safety concerns to prevent contamination and spoilage. Some ingredients have a different shelf-life based on the storage condition. Transportation conditions may also be listed here.

Shelf-Life – If applicable, a duration of time will be stated when the product should be used. Sometimes this date will be based on the production date or the date the package is opened. Many different titles are used for this date such as Best by Date, Use by Date, or Expiration Date. There have been recent efforts to standardize shelf-life verbiage to “Use By,” which would be used for perishable products after which date the food should be discarded, and “Best if Used By,” which is the date after which a product could be safely consumed but would not be at optimal quality.

Allergen Status – Food allergens are a major concern. Each ingredient should have either a statement or a table that indicates whether there is a presence of an allergen. Some statements will go a step further and provide allergen information for the line or equipment that the product is produced on, present at the production site, or if there is any possibility of cross-contact.

EXAMPLE: Fine Foods is looking to change suppliers for their basil herb to a new supplier. Their current specification documentation is clear on the limit and includes units for microbiological tests. They know those test methods and dilution factors will need to be aligned to meet their needs.

After reviewing test methods, Fine Foods identifies that their specification for micro is <10 cfu/g. The new spice supplier’s method has a specification stated as <100 cfu/g. As a result, the spice supplier’s testing is not as precise as Fine Foods’ current standards. Reporting a result of <100 cfu/g may be out of specification if the requirement is <10 cfu/g.

Things to consider in this situation:

1. Does the new supplier use the same test methods and dilutions?
2. Can the new supplier adjust their specifications to meet <10 cfu/g?
3. Does this specification change affect the final product’s specifications? If the higher specification does not affect the final product, then consider changing the requirements for these ingredients. You would want to make sure that any raw ingredient specifications do not exceed finished product specification (i.e. if the product this herb is used on has a <10 CFU/g specification, it would not make sense to accept a raw ingredient at <100 CFU/g as that produces extra risk to the product being out of specification)
4. Can the new supplier only supply batches that meet the <10 cfu/g specification? Depending on historical results, this may create supply delays due to every batch is not required to have the lower results.

Overall Summary

Growing your business is very important and growing it safely is your responsibility. Hazards exist that can impact the food safety of your product.

Sourcing materials from trusted suppliers is the best way to limit this risk. Trust is built through transparency and communication with your supply chain.

We hope you found this packet informative and easy to use so you can implement your supplier control food safety plan and programs to help keep people safe and your business thriving.

Be sure to visit the following links for templates and request forms:

APPENDIX A – Sample Questionnaire

APPENDIX B – Questionnaire Template

APPENDIX C – Documentation Request

APPENDIX D – Generic Technical Data Sheet

For more comprehensive guidance and access to workshops and risk assessment tools, visit www.usdairy.com/about-us/innovation-center/food-safety/supply-chain.

The information provided herein is for informational purposes only. The Innovation Center for U.S. Dairy (“the Innovation Center”) makes no representation or warranty with respect to the completeness, accuracy, reliability, or suitability of any information contained herein. We recommend that practitioners consult an attorney concerning the laws applicable to any particular situation as well as their own scientific experts to evaluate the applicability of any recommendation to their particular situation. By utilizing the materials contained herein, you agree to release the Innovation Center from any and all liability that may result from your use of the information provided.



*These tools were curated in collaboration with a team of industry, trade association and academic volunteers. If you think a resource or contact is missing, please let us know innovationcenter@usdairy.com

A special thanks to Michelle Matto (AM Food & Nutrition), Bob Wills (Cedar Grove Cheese), Alex O'Brien (WI Center for Dairy Research), Katie Phillips (Dairy Connection), Adam Brock (Dairy Farmers of Wisconsin), Tim Stubbs (Dairy Management Inc.), Danielle Quist (International Dairy Foods Association), Pat Mugan (Sartori Cheese), and Mary Wilcox (Significant Outcomes LLC), for their contributions.