



Resources for Growing Your Business Safely

# Ice Cream Inclusions

Food Safety Guide



*Developed in collaboration with a team of small business owner, processor, trade association, and academic volunteers.*

## Overview

It's an exciting time to be making ice cream. Consumption is growing around the globe and consumers continue to look for unique experiences through gourmet inclusions and new flavor options - but sometimes being creative can introduce new risks. When introducing new innovative inclusions, they will need special care, handling, and usage. Addressing these needs through effective food safety programs is an important way to protect your customers and minimize the risk of a product recall for your business. Because of the need to inform the public, recalls can damage the reputation and credibility of a company and even an entire industry. A single recall can financially devastate a small business, forcing them to shut their doors and close a shop.



This guide is intended to be used as a reference when developing your food safety program as it pertains to adding flavors, ingredients, inclusions, and variegates to ice cream with information on 1) biological (pathogens) 2) chemical (allergens), and 3) physical hazards (foreign materials i.e., hard plastic, glass, etc.). For the purposes of this guide, we refer to anything added to your pasteurized mix as an 'inclusion.' In writing this guide, a basic level of understanding of cleaning/sanitation, hazard identification, pathogens, and Good Manufacturing Practices (GMP's) by the reader was assumed.

For additional information on these topics, an [online training course](#), [easy-to-use templates](#), [guidance documents](#), [workshops](#), and other [resources](#), may be found at [safeicecream.org](http://safeicecream.org).



## Identifying Hazards

It is imperative that a thorough hazard analysis and risk assessment be completed to identify and control anywhere your product could be contaminated. Hazards (physical, chemical, and microbiological) are in every facility. Assessing, controlling, and eliminating these risks is important for ensuring the safety of your product. In a [risk assessment](#), one would look at each step in your process to consider the introduction of any of contaminants as a potential hazard and then identify appropriate control strategies to reduce or prevent the occurrence of the hazard. Because many ingredients in ice cream manufacturing are added to a pasteurized 'mix,' it is imperative to reach out to your suppliers to understand their hazards and risk reduction strategies as well. Just because an ingredient is fresh, does not mean that it is safe. This false assumption has been brought to light during recent recalls. Having a food safety program with preventative controls for hazards helps enhance the quality of your product, maintains business excellence, and protects the health and lives of your customers.

## Consider the following:

- Which products, ingredients or inclusions have allergens?
- How will you prevent cross contact between ingredients? Between flavors?
- How are the ingredients stored to avoid cross-contact?
- What checks do you have in place to ensure accurate labeling on the final product?
- Do you have dedicated utensils for ingredients and products that contain allergens and separate utensils for non-allergen containing foods and ingredients?
- Do you have a validated cleaning step between processing ice creams with different allergens?
- Do you have a color-coding system in place to help avoid employee confusion?
- What training programs do you have in place to ensure employee understanding?

For additional information on these topics, an [online training course](#), [easy-to-use templates](#), [guidance documents](#), [workshops](#), visit [safeicecream.org](http://safeicecream.org).

## Microbial/Pathogen Risks

### *Fresh vs Treated for Safety*

Ensuring the microbial safety of your products involves good sanitation, using pasteurized mix, and ensuring that all your inclusions are pathogen free.



Milk, cream, eggs, and other major ingredients in ice cream could carry a variety of pathogens. Therefore, your ice cream mix needs to be pasteurized and then kept free from contamination after pasteurization. Mix is your biggest ingredient, and if contaminated with a pathogen from an ingredient or inclusion, it may provide a great environment for potential microbial growth because of its high moisture, neutral pH, and nutritious composition. Proper pasteurization will eliminate pathogens of concern but cannot protect the product from re-contamination. Reintroduction of pathogens could still put your product at risk, so ingredient, process and sanitation controls are very important. In general, everything added after pasteurization should be “Ready to Eat” (RTE), which may require the vendor to take additional steps to ensure the safety of the ingredient. RTE versions of common ingredients may be more expensive, but they are necessary to ensure you do not unintentionally contaminate your products. We will cover more information on biological hazards and best practices for some commonly used ingredients later in this document.

***Raw, unpasteurized commodities should never be used to make ice cream!***

## Allergen Risks

### *Cross Contact and Labeling Considerations*

According to the Food & Drug Administration (FDA), undeclared allergens are the number one cause of food recalls in the United States. In the United States, the FDA requires special Labeling, declarations, and practices for the “Big 9” allergens: **milk, peanuts, eggs, tree nuts, wheat, soy, fish, sesame, and crustacean shellfish.**

Ice cream's wide array of flavors means a consumer can find their perfect combination of inclusions (e.g., chocolate, nuts, caramel, cookie dough or key lime with graham cracker) to satisfy their taste buds. However, these inclusions can cause serious health consequences to individuals who are allergic if undeclared and consumed in a food product. This could be due to either accidental cross contact (e.g., carryover on equipment or as an ingredient in an inclusion) or from a failure to properly list an ingredient on the product label.

Take a moment to consider your recipes and what your consumers are expecting. Traditional ice cream contains dairy. Unless you have labeled your product as "non-dairy," "dairy-free" or "soy based" it is generally accepted that consumers should expect dairy as an ingredient. However, you will still need to declare "milk" on the label.



### Consider the following:

- Would you add milk chocolate chunks to soy ice cream? No. If you produce a non-dairy variety, it is important to make sure all your inclusions are also dairy free.
- What about cleaning equipment when switching between soy (an allergen) and milk/cream (an allergen) based recipes? Yes, you are required to clean and sanitize between batches
- Should you schedule non allergen containing products before flavors containing allergens like nuts and peanuts to prevent cross-contact? Yes.
- Would you ever think of a shellfish allergen in ice cream? Fish gelatin can be an ingredient in marshmallows. This is a great reminder of how imperative it is to check the ingredient declaration of every ingredient used in your ice cream and so that you make your customers aware of all allergens in the product.

For more detailed guidance visit: <https://www.fda.gov/media/172318/download?attachment>

### Importance of Labeling

When labeling, it is important to identify on the label any allergens. It is also important to include the specific tree nuts, fish, and crustacean shellfish that are used because people have different allergies. For example, a person may be allergic to pecans but not to almonds. Coconut is also considered a tree nut in the United States, and its presence must be declared on the label. Being aware, controlling these hazards, training all personnel on allergen controls, and ensuring the correct allergen specific information is on your label is crucial to your allergen control programs.

## Physical Risks

### *How to Protect Your Products from Foreign Material Hazards?*

A “Foreign Material” is any item that is not a natural component of a food. It can be a food safety hazard and must be included in the hazard analysis for a food safety plan. FDA defines a foreign object as, “hard or sharp foreign objects in food may cause traumatic injury including laceration and perforation of tissues of the mouth, tongue, throat, stomach and intestine as well as damage to the teeth and gums.” They further define it as: “product contains a hard or sharp foreign object that measures 7 mm to 25 mm, in length”. Even objects that do not meet this legal definition can harm customers and your business (e.g., pits are expected in cherries, but are not expected in ice cream).

Foreign materials in your product could harm a customer and impact your business, so committing to enhancing your food safety programs benefits your company in many ways. Examples include conducting supply-chain reviews, inspecting ingredients when they arrive at your facility, conducting routine glass and brittle plastic self-audits of your facility, and anything else you identify for your operation. See Supplier Controls Section for more detailed guidance.

When building and designing your own food safety program, it is important to use a cross functional team to help identify potential foreign material introduction sites. Creation of a well-rounded team enhances buy-in and creates a positive food safety culture. Broad participation beyond the food safety and quality team results in many sets of dedicated eyes focused on identifying potential issues and a passionate workforce protecting your facility and brand.

## Best Practices for Common Inclusions

### *Fruit Best Practices*

Fruits may be used whole, sliced, crushed, diced, or pureed. Getting local berries and produce from a farm stand may be considered fresh, but growers may not have all the safeguards in place that you need for using their commodities as inclusions in your finished product. The use of fresh fruit is discouraged because they have a history of being implicated in foodborne illness outbreaks. If fresh fruit is used, you will need to identify all the hazards associated with this product (biological, chemical, and physical) and develop/document a control for each hazard.

Many commercial produce processing plants sanitize their wash water to prevent the spread of any contaminants to other fruits/vegetables, but this not a satisfactory control on its own. Heat treatment and/or microbial analysis are also required. Fruits like cherries, which are heat stable, should be purchased heat preserved. Whether frozen packed or heat preserved, a Certificate of Analysis (COA) with microbiological parameters should be obtained from the supplier for every lot received.



## **Egg Best Practices**

Most ice cream manufacturers use frozen or powdered pasteurized egg yolk in ice cream mixes for emulsification. For custard/French ice cream, a minimum of 1.4% egg yolk solids is required. Egg is a major allergen; therefore, all necessary precautions should be taken to prevent cross-contact during receiving, storage and processing of egg yolks or egg whites. The use of fresh eggs is highly discouraged (unless you pasteurize the mix after they are added) because of the prevalence of *Salmonella* and other pathogens in raw eggs. Using pasteurized eggs from a reputable source is the best practice. Because eggs have a history of being implicated in *Salmonella* outbreaks, a Certificate of Analysis (COA) for pathogens should be obtained. Having a robust supplier verification program helps ensure the safety of this commonly used inclusion and your finished products.

## **Cocoa Best Practices**

Cocoa powders and pre-sweetened cocoa powder blends usually are sterilized by the vendor through the bean grinding process. When cocoa beans are received, they are sifted and sent through a metal detector to filter out larger foreign material. Cocoa beans are sterilized either in the whole bean state or in the nib (broken bean, minus shell) state, steamed at a minimum of 230 degrees Fahrenheit for a minimum of six minutes. The nibs are then roasted before they are pressed at a high temperature to create cocoa liquor cake. The cocoa liquor/cake state is likely the product you would use to make chocolate ice cream. All the major suppliers of cocoa powder go through this sterilization process. To ensure that you are receiving good quality cocoa powder, you should only buy from approved suppliers that will supply you with certificates of analysis (COAs) and have a food safety program in place.



To add cocoa powder to ice cream mix, it is recommended to make a chocolate slurry. Since water can be source of biological hazards, all water sources should be evaluated on a frequent basis prior to use. Additionally, water or mix should be heated before adding the cocoa powder, which will aid in providing a better blended product. When adding the cocoa slurry to your pasteurized mix, make sure you are following all your GMPs, so the product does not become contaminated. Some state regulations require another heat treatment step after adding the cocoa powder. Be sure to check with your state

regulatory offices to know whether this is a requirement you must meet. Go to [Safeicecream.org](https://www.safeicecream.org) for an [interactive map](#) of experts to help locate the one near you.

## ***Nut Handling Best Practices***

Nuts are a common inclusion used in many types of ice creams. Although they are a delicious inclusion, there are many risks to consider when adding nuts or nut-containing items to your products.

First, all types of nuts are allergens, which are required to be listed, both on the ingredient statement and allergen statement of your finished product label. Each type of nut used must be declared in your ingredient statement, since people can be allergic to certain species of tree nuts, but not necessarily all of them. For example, if someone is allergic to peanuts, they may be able to consume pecans with no reaction.



Secondly, nuts are a common source of pathogenic bacteria, such as *Salmonella*, pathogenic *E. coli*, or *Listeria monocytogenes*. For this reason, nuts should always be processed using a scientifically validated treatment before being added to ready-to-eat (RTE) items by you or your supplier. Various thermal treatments applied to nuts can include roasting, blanching, and frying. If you choose to use nut butters as an inclusion, they should also be free from pathogens. It is best practice to request that your supplier conducts analysis, including pathogens and mycotoxins, on any nut products. Additionally, a robust sampling and verification program should also be put in place to make sure that these pathogens do not enter your facility.

## ***Herbs & Spices Best Practices***

Herbs and spices are a creative addition to include in your ice cream. However, during processing ice cream can be susceptible to microbial growth. Untreated spices may contain biological hazards including pathogens and mycotoxins; therefore, it is imperative that all spices are properly handled and pre-treated by a reputable supplier to mitigate these risks. Additionally, because spices can be expensive, they are considered at higher risk for food fraud related activities. Food fraud occurs when a supplier substitutes a cheaper, alternative item in place of the item that is ordered for monetary gain. For example, foreign objects or substances, such as sawdust, have been used as a “filler” in some spices. Spices may also be contaminated with heavy metals. Consequently, you or your supplier should conduct thorough testing on each batch of spices. You may also consider including organoleptic testing to ensure you get the flavors you are expecting in every batch.

## ***Powdered Ingredients Best Practices***

Dried, minimally processed powders such as milk powders, stabilizers, etc. can also be a potential source of bacterial contamination. Bacteria such as *Salmonella*, pathogenic *E. coli*, *Listeria monocytogenes*, *Bacillus cereus*, and *Staphylococcus aureus* can be found in them. Due to the risk involved in adding powdered ingredients to liquid mixes and products, many states require pasteurization, or an alternate form of risk mitigation, for these items. Even with pre-treated items, when a powdered ingredient is added to a liquid, that mix is now considered to have reverted to a raw state and requires further thermal processing prior to consumption.

## Supplier Controls



Whether you purchase your goods from a local farm or a global supplier, knowing who you purchase from, and their practices can help protect you and your business. It is in your best interest to learn about each of your suppliers. The Food Safety Modernization Act states that you are responsible in the event of a recall.

If you do not take the time to gather important supplier information and document it, you are assuming all the risk for every ingredient that goes into your ice cream. This includes any microbial contamination, as well as any uncontrolled cross contact of an allergen.

### ***Importance of Approved Suppliers***

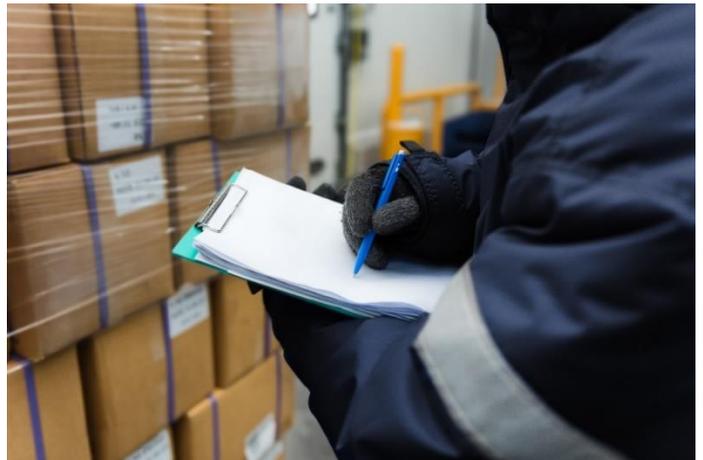
How do you locate your suppliers? Do you get your ingredients and inclusions from a broker, individual ingredient suppliers, a big box store, or the farmer down the road? Are your packaging, chemicals, and industrial lubricants all food grade? How would you find out?

A good supplier will be able to provide you with proper information and documentation that the product(s) you are purchasing meets predetermined food safety and quality attributes. For example, they may test for microbial contamination on their produce. This information is extremely important so that you can be assured you are not adding biological hazards to your ready-to-eat (RTE) product.

Although highly qualified suppliers may not be the cheapest option, they can save you money in the long run and provide a sense of security knowing that the ingredients you are adding to your products are as safe as possible, properly labeled, and handled correctly through distribution. When you work with a vendor, you should have a lot of questions for them- everything from requesting a copy of their food safety plan to how they train and enforce employee hygiene.

A supplier questionnaire can be a helpful tool to gather all the necessary information. As a food manufacturer, you have the right and responsibility to audit your suppliers and make sure they are implementing proper controls. It is your responsibility to ensure that your supplier is controlling the inherent risks associated with the item being purchased.

(To help you with this, see linked [Supplier Questionnaire](#) and [Verification Document](#))



Before approving a vendor, a specification sheet should be written or obtained from the vendor which describes a product's intended use, ingredient statement, allergen information, storage condition, microbial limits, and shelf life. [Generic Technical Data Sheet](#). In addition, a Certificate of Analysis of each lot of ingredients should accompany each shipment. The best way to ensure you are receiving safe ingredients and packaging from your suppliers is to develop an approved supplier program

## ***Inspection and Handling of Received Materials***

Inspection of raw materials and ingredients to ensure they are suitable for use in food manufacturing is important. It is common practice to require suppliers of raw materials and ingredients to provide COAs, which are records of detailed analytical and microbial parameters specific to the lot of materials being delivered. To successfully verify the provided COA, an item specification must be requested and kept on file for each item that is used. A trained employee must review each COA to confirm that the specifications are met and that the lot number on the COA matches the lot number of the item received. If an item is received and used that is outside of the agreed upon specification, the responsibility falls on the finished product manufacturer. Inspect all vehicles used to transport your product or ingredients and monitor your shipments regularly for appropriate temperature and humidity ranges. Accept incoming materials only after confirming that the materials possess sufficient food safety and quality for use in your facility. (See [Receiving Documentation](#)).

Having a [Supplier Controls Program](#) in place to monitor for hazards is important for ensuring the safety of finished products.

Store all food materials at proper temperature and humidity and in containers that are constructed to prevent adulteration. Label containers with pertinent information such as type of material, date of receipt and whether the product has been reworked and follow the principle of FIFO- first in, first out. Take a critical look at how you store ingredients and consider physical separation to reduce the risk for allergen cross contact. Always label allergens clearly and store non-allergens above allergens. To easily differentiate the allergens, consider labeling with icons or color coding. The International Association for Food Protection (IAFP) has [icons](#) you can use to label pallets and containers as they are received.



## ***Importance of Documentation and Recordkeeping***

Additional recordkeeping is required if you manufacture, process, pack, or hold foods that are on the [Food Traceability List](#). This list includes items such as nut butters and fruits that may be included in your finished product. . ntainig records containing Key Data Elements (KDEs) associated with specific Critical Tracking Events (CTEs) is required, and in the event of a recall, all information must be provided to FDA within 24 hours. All record keeping requirements must be in place by January 20, 2026. The FDA has issued a [Small Entity Compliance Guide](#), and additional information on Key Data Elements and Critical Tracking Events can be found at [Food Traceability Rule: Critical Tracking Events and Key Data Elements \(fda.gov\)](#)

## **Grow Your Business Safely: The Importance of Protecting Consumers and Preventing Recalls**

Development, implementation, verification, and documentation are vital to the effectiveness of food safety programs. Your programs are important to minimizing the risk of food borne illness and product recalls - what you do now protects the future of your customers and your business.

If you need help, resources are available. Visit [www.safeicecream.org](http://www.safeicecream.org) to access an online training course, easy-to-use templates, workshops, and a link to one-on-one technical support. Most states and regions also have local extension representatives who can assist you. You can also visit associations like [NAICA](#), [IDFA](#), or the [Innovation Center for US Dairy](#) for additional resources.

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