Guidance Document
For
Mail Order Food Companies

Approved at the 2018 Biennial Meeting of the CFP

Prepared by the
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2016-2018 Conference for Food Protection

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Preface

Council III of the Conference for Food Protection (CFP) formed the Mail Order Food Safety Committee, in response to Issue 2016-III-037, which was charged to:

1. Identify best practices and existing guidance documents that relate to shipment directly to a consumer of perishable food items.
2. Develop a guidance document for food establishments that includes best practices for transportation directly to a consumer of perishable products, to include proper packaging; temperature control during shipping, receiving, and storage; return of compromised and abused products; and other food safety related topics.
3. Determine appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.
4. Report the committee's findings and recommendations to the 2018 Biennial Meeting of the Conference for Food Protection.

Charge No. 1: Prior to commencing development of the guidance document, the Committee researched multiple publications already in existence, both in part and in full, to gather an idea of what guidance was already available to companies and what was lacking. The initial version of this guidance document was drafted based on an existing publication: "*Industry Guide to Good Hygiene Practice: MAIL ORDER*" in support of Regulation (EC) No 852/2004 on the Hygiene of Foodstuffs and the temperature control requirements of the Food Hygiene (England/ Scotland/ Wales/ Northern Ireland) Regulations 2006. While this publication provided the foundation of the guidance document, the finalized version submitted herein is an original work of the Committee.

Part 1. Introduction

This guidance document is intended for food establishments delivering perishable foods to the consumer by mail order. It includes best practices for transportation of perishable food items directly to a consumer including parameters critical to preventive controls, mechanisms to assess risk, validation and verification practices, recommendations for proper packaging, temperature control during mailing, receiving and storage, physical and chemical contamination control, allergen control, general food safety information, and suggestion for return of compromised and abused products. The intent of the guide is primarily to provide best practices for preventing biological, physical and chemical contamination, as well as the growth of harmful bacteria and/or the formation of toxins within the food being shipped. Foodborne illness may occur if products are not prepared, packed and shipped using sanitary conditions and proper temperature controls.

The use of this guide by businesses is voluntary. The information contained will help companies selling food via mail order understand relevant regulations that may pertain to their operation, risks associated with shipping perishable foods, and ways to manage food safety risks throughout the entire shipping process. Beyond the safety and protection of the consumer, following these suggested best practices should assist the mail order food company with maintaining or even improving the quality and consistency of the services they provide.

Disclaimer: The guidance provided in this document does not take precedence over any local, state, or federal regulatory requirements for operating a mail order food company. Businesses need to contact the proper regulatory authority for operational compliance requirements, including any required licenses or permits.

Part 2. Definitions

Active managerial control: the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors.
Broker: An independent sales agent that works in negotiating sales for food manufacturers. Food brokers work for both manufactures and buyers of food as they help "broker" deals to sell food products to a variety of buyers.
Eutectic: the lowest possible temperature of solidification for any mixture of specified constituents. Used in this document as related to a type of coolant for passive refrigeration.
First in First out (FIFO): a method of inventory accounting in which the oldest remaining items are assumed to have been the first sold.
Food employee/handler: an individual working with unpackaged food, food equipment or utensils, or who handles open/exposed, wrapped or packaged food, packaging and other food equipment, including food contact surfaces.
Food Establishment: as per the FDA Food Code, an operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human

consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank; and (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or deliver service that is provided by common carriers.

Hazard: a biological, chemical, or physical substance in food that may cause an unacceptable consumer health risk.

Mail order food company: a business organized to promote, receive, prepare, fill and ship orders of food through the mail or by common carrier.

Mail order: for the purposes of this document, "mail order" is used throughout to include all distance-selling operations that use passive temperature control for the delivery of products, irrespective of how orders are received (e.g. by mail, telephone, fax, email, internet).

Mechanical refrigeration: often simply referred to as refrigeration. The use of powered refrigerator units to cold-hold and/or cool foods to their required safe food temperatures.

Passive refrigeration: A method of maintaining perishable foods at safe temperatures without the use of powered refrigerator units.

Pathogen: a microorganism of public health significance.

Perishable foods: for the purpose of this document, foods that are required by law, to remain at specific chilled/refrigerated food temperatures for product safety. They are also referred to as time/temperature control for safety foods or TCS foods. They have been historically called potentially hazardous foods (PHF).

Preventive controls: risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent hazards identified by a hazard analysis, which are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Ready-to-Eat (RTE): food that is in a form that is edible without additional preparation to render it safe for consumption.

Regulatory authority: the local, state, or federal enforcement body or authorized representative having jurisdiction over the food establishment.

Risk: the likelihood that an adverse health effect will occur within a population as a result of a hazard in food.

Shippers: parcel delivery services available in the United States, such as the US Postal Service (USPS), FedEx, or United Parcel Service (UPS).

Slacking: the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -23 to -4 °C (-10 to 25 °F) prior to cooking. Thawing is different from slacking and details on thawing can be found in section 3-501.13 of the FDA Model Food Code.

Time/Temperature Control for Safety (TCS) food: a food that requires either or both specific time and/or temperature requirements to limit pathogenic microorganism growth or toxin formation.

Validate: obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verify: the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Part 3. Scope

The nature of the food product being shipped (refrigerated, frozen, fresh produce, dry goods, etc.) will necessitate different handling requirements. Individual recommendations will be noted for each type of food throughout this guide when applicable. A mail order food company should be aware that foods provided to a consumer as a "free gift" or sample are not exempt from regulatory requirements, even if there is no charge to the consumer for the item.

The method by which mail order foods reach the final consumer can vary significantly. The product may be produced and sold by the mail order food company directly to the consumer. The mail order food company may also buy products from various distributors or retailers and then repack these items for shipment to the consumer. There are a range of existing industry and regulatory guides (see Appendix A) that provide guidance and advice on regulatory requirements and good manufacturing practices. There is no "one size fits all" approach in this guidance, but rather the document aims to provide the essential parameters that should be considered and employed by the mail order food company in order to provide a safe food product to the consumer.

This guide does not cover:

- The local delivery of foods intended for immediate consumption from restaurants, grocery stores, or other food establishments to the consumer. (e.g. pizza delivery).
- The transportation of food in mechanically refrigerated vehicles.
- Export requirements, tariffs or customs aspects of international deliveries.

Part 4. Temperature control and use by dates

Regulatory requirements

There are requirements in federal, state and local regulations that govern mail order foods and details are provided in Appendix A. These food safety regulations require certain foods to be held at temperatures adequate to prevent the growth of harmful bacteria or the formation of toxins, including during transportation and delivery to the final consumer via mail order.

State, territorial and local regulations modeled after the FDA Food Code require retail food establishments to follow practices that prevent food from becoming adulterated or unsafe. These include establishing the maximum temperature at which TCS foods must be held during

storage and display. For most TCS foods, the FDA Model Food Code establishes a maximum cold-holding temperature of 5 °C (41 °F) to limit the growth of pathogenic bacteria during storage and display. Other temperature limits may be appropriate for perishable foods that do not require temperature control for safety, but that are kept cold to preserve quality and limit the growth of spoilage organisms.

The FDA Food Safety Modernization Act (FSMA) includes a rule on Sanitary Transportation of Human and Animal Food. This rule is designed to prevent transportation practices that create food safety risks (e.g. failure to properly refrigerate food, inadequate cleaning of vehicles between loads, etc.). The new FSMA Sanitary Transportation rule builds on the 2005 Sanitary Food Transportation Act (SFTA) and establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food. These requirements mandate a company to use sanitary practices to ensure the safety of that food. The requirements do not apply to transportation by mail or air because of limitations in the law.

For more information on FSMA Final Rule on Sanitary Transportation of Human and Animal Food, look here: https://www.federalregister.gov/documents/2016/04/06/2016-07330/sanitary-transportation-of-human-and-animal-food.

During shipment for delivery, establishing the appropriate time and product temperature limit is important. In establishing product temperature limits and the duration for which those limits may be exceeded, the mail order food company should assess the microbiological risks posed by the product and assure they are adequately controlled until receipt by the final consumer. An example of appropriate data could be obtained using simulated time and temperature studies for packages during shipment. Resources for obtaining that supporting technical or validation data are detailed below.

FDA has indicated several waivers from the Sanitary Transportation rule, which are detailed here: https://www.federalregister.gov/documents/2017/04/06/2017-06854/waivers-from-requirements-of-the-sanitary-transportation-of-human-and-animal-food-rule. Mail order food companies should contact the proper regulatory authority to determine if they are covered by the waiver. For specific questions regarding the Final Rule on Sanitary Transportation of Human and Animal Food or the waivers, contact the FDA Outreach and Information Center https://cfsan.secure.force.com/Inquirypage or the FDA Center for Food Safety and Applied Nutrition: https://www.fda.gov/Food/ResourcesForYou/ucm334249.htm

Prior to mailing

Mail order food companies should handle foods in accordance with the guidance provided in this document prior to mailing. Although limited periods outside temperature control are permitted during preparation, cooking, cooling, or packaging (prior to mailing to the consumer), the acceptable limits will depend upon the combination of time and temperature.

Product temperature target during mailing to the final consumer

During mailing, the food temperature must be maintained appropriately. Thus, if product temperatures are likely to rise above 5ºC (41ºF) in transit, the mail order food company should be confident the microbiological risks posed by the product are managed until receipt by the final consumer by reference to supporting technical or other validation data. Any example of appropriate data could be obtained using simulated time and temperature studies for packages during shipment. Resources for obtaining supporting technical or validation data are detailed below.

Businesses that target same day delivery or overnight delivery and that can control the longest possible delivery time (e.g. restricting delivery ZIP code) could develop a risk control plan (sometimes called a validation study) to demonstrate their control of the distribution chain and their ability to limit the growth of pathogenic organisms. Businesses that have less control over delivery times must account for this variability. Risk control plans should take into consideration the type of food, the organism(s) of concern, and the growth limit targeted. Risk control plans should be supported by relevant scientific or technical literature, pathogen predictive growth models or actual bacterial growth experiments. For example, the procedures for handling refrigerated TCS food during a power outage provides a representation of adequate risk control plan suitable for use in a specific situation (e.g. emergencies, See the 2014 CFP – Emergency Action Plan for Retail Food Establishment, http://www.foodprotect.org/guides-documents/emergency-action-plan-for-retail-food-establishment/.

Validation and verification

Validation: Any business wanting to engage in mail order food operations should understand the need to set critical temperature limits to protect public health and then must verify that the controls put in place are adequate to maintain those limits.

The mail order food company should be able to demonstrate how product temperature will be maintained in "worst case conditions." Examples of worst case conditions include: when the external ambient temperature reaches historic highs, when the delivery time is extended, when the product is left outside upon receipt to the delivery location for an extended period of time, and/or when the shipment has a low thermal mass or a high volume. Companies who manufacture shipping containers for food or suppliers of mailing containers may be a good source of validated studies for temperature control under different time and temperature parameters.

A validation may be deemed successful when an external independent laboratory can repeatedly simulate "worst case scenarios" and show that the product temperatures are lower than the targeted temperature at the end of the longest possible delivery time. For businesses that do not restrict state or ZIP code of consumers, Phoenix AZ, Dallas TX, and Miami FL could be considered as candidates for the farthest, warmest location (depending where the food ships from).

Validations should be performed before the mail order food company begins mailing product and any time an essential component of the distribution chain is modified (e.g. extended zone of delivery, change in packaging, etc.). Deliveries should not commence until the validation demonstrates control and deliveries do not exceed the validation parameters. For existing companies already mailing product, validations should be performed as soon as possible. If validation data are not available, temperature checks on receipt should be performed in sufficient numbers to assure control and the safety of the food.

Verification: While validations are suitable to demonstrate compliance prior to business launch, a verification program is recommended to confirm that products arrive at or below the targeted temperature under real operating conditions. When verification results are unfavorable, corrective actions to improve temperature control should be implemented. Such corrective actions might include use of additional ice packs or coolants and/or a change in package insulation. Consumer returns and complaints may also be a useful measure of assessing temperature control.

Both validation and verification records should be kept for a suitable period of time, and made available to regulators upon request. Not only is this information an essential component of food safety for a mail order food company, it is also critical for ensuring that the products purchased by consumers are wholesome, unadulterated, and safe to consume.

Passive refrigeration preventive control parameters

Passive temperature control relies on a combination of parameters. These parameters can include mailing time, the insulation of the container used for transportation, the type and amount of coolant (e.g. ice pack, dry ice), or the mass and the initial temperature(s) of the product(s). All these parameters can interact together to assure a suitable temperature on receipt.

The efficacy of the coolant depends on the temperature at which it changes physical state as well as the mass and type of coolant. Although ice packs thaw at 0 °C (32°F), gel packs can thaw at temperature below 0 °C (32°F) depending upon their composition. Dry ice is commonly used as a coolant in the delivery of frozen food and it sublimates at -78.5°C (-109.3°F).

Temperature control requirements for food safety

Proper temperature control from the time the food is received by the mail order food company until the point where the food is received by the consumer is an integral part of any mail order food safety program and the focus of this section. Maintaining food at proper temperatures is critical to limiting the growth of pathogenic bacteria or the formation of microbial toxins in food. Mail order food companies must handle food safely during all phases of the operation to ensure that food received by consumers is wholesome, unadulterated and safe to consume.

Food facilities, including food manufacturing facilities and retail food establishments where food is prepared for the mail order food company, are regulated by applicable federal, state and

local food safety statutes. It is important that companies understand all legal requirements and industry guidelines for temperature control and design systems to comply with all legal requirements prior to packaging, mailing and transporting food. Mail order food companies should research, understand and test which methods are best suited to their specific operation. Below are references which may help in this process.

Relevant resources regarding temperature control

- 2013 FDA Food Code Chapter 3 (Food), especially the section 3-5: Limitation of growth of organisms of public health concern https://www.fda.gov/downloads/food/guidanceregulation/retailfoodprotection/foodcode/ucm374510.pdf
- FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm
- FDA Fish and Fishery Products Hazards and Controls Guidance https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm
- USDA Food Safety Information: Mail Order Food Safety https://www.fsis.usda.gov/wps/wcm/connect/9020369a-247f-423c-8486-7e31ca6bcfc3/Mail_Order_Food_Safety.pdf?MOD=AJPERES
- U.S. Department of Health & Human Services: Food Safety for Home Delivered Meals https://www.foodsafety.gov/risk/deliveries/index.html
- Some states may have specific requirements for temperature control. Contact the state health department that has jurisdiction over food regulations for details.

Relevant resources regarding pathogen growth risk

- US FDA Hazard Analysis Critical Control Point (HACCP) guidance https://www.fda.gov/Food/GuidanceRegulation/HACCP/default.htm
- FSIS Compliance Guideline HACCP Systems validation April 2015 https://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation.pdf?MOD=AJPERES
- FDA Guidance for Industry: Control of *Listeria monocytogenes* in refrigerated or frozen ready-to-eat-food https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm073110.htm
- CFP Emergency Action Plan for Retail Food Establishments http://www.foodprotect.org/media/guide/Emergency%20Action%20Plan%20for%20Retail%20food%20Est.pdf
- USDA Pathogen Modeling Program https://pmp.errc.ars.usda.gov/PMPOnline.aspx
- ComBase Predictor https://www.combase.cc/index.php/en/

Advice on good practice

All temperature control provisions relate to the temperature of the food and not the air temperature in the mailing container. When decisions are to be made regarding the safety of a food, it should be ensured that temperature readings taken represent the food.

There may be some cases where the normal maximum temperature of 5 °C (41°F) is not cold enough, such as in the case of Reduced Oxygen Packaged (ROP) fish, which must remain frozen. Such foods should be labeled as necessary to ensure safe handling.

The mail order food company should ensure that the product mailed arrives to the consumer with adequate time left in the shelf life. Mailed foods should include shelf life information to assist the consumer in managing safety and quality. Unless the product is frozen, the storage time prior to shipment should be minimized and the holding temperature maintained at 5°C (41 °F) or below.

When foods are prepared by another entity and included in the shipment by the mail order food company, the mail order food company should work with the supplier to ensure that the shelf life applied to the food is appropriate. This discussion should include temperatures that the product will be subjected to throughout mailing, receipt, storage and consumption by the consumer. When foods are prepared and packed by the mail order food company, the company should ensure that temperature requirements appropriate to the food are followed (e.g. frozen, TCS and non-TCS).

The packaging used in transit will be a major factor in maintaining the food at a safe temperature. Section 5 (Packaging and Mailing to the Consumer) contains guidance on the kind of packaging and refrigerants available and how best to use them.

Procedures for taking food temperatures

Temperature can affect safety, shelf life, quality and processing characteristics of foods. Several different types of thermometers are used to monitor the temperature of foods, including: bi-metal stemmed, digital, thermocouple and infrared types. Depending on their specific usage, these devices have advantages and disadvantages as described below.

Type of Thermometer	Advantages	Disadvantages
Bi-Metal	Small – fits in pocket Can be used with most foods Inexpensive Can be calibrated	Slow response time Not suitable for thin foods Narrow range (0 to +220 °F) Less accurate Sensor located 2 ½" from tip
Digital	LCD display – easy to read Wide temp range (-50 to +300 °F) Sensor located at tip	Unable to calibrate Most are not waterproof
Thermocouple	Very wide temp range (-60 to +2000F) Quick response time Very accurate Ideal for all food temp's	Must be factory calibrated
Infrared	Fast response time Wide temp range (-25 to +900 °F) Food contact not required Non-destructive	Measures surface temperatures only Not suitable for regulatory purposes

Employees preparing food within the mail order food company prior to shipment should be trained to know what different thermometers are used for and how to maintain them to ensure they work properly. Thermometers need to be washed, rinsed, sanitized and air dried before and after use to prevent cross-contamination.

Any food temperature measuring devices should be readily accessible for use and stored in a clean manner. Regulatory guidance suggests that food temperature measuring devices be calibrated in accordance with manufacturer's specifications (including frequency and method of calibration) to ensure their accuracy.

TCS food temperatures should be monitored and controlled in the following stages:

- Receiving
- Refrigerated storage
- Freezer storage
- Cooking
- Hot and cold holding
- Cooling
- Reheating
- Packing
- Mailing

Temperatures should be measured and recorded at appropriate frequencies and corrective actions should be taken when deviations are identified.

The FDA Food Code temperatures are given in Part 3-2, 3-4 and 3-5. However, mail order food companies should check with local jurisdictions for any local or state variations.

The application of a use by date

The purpose of this section is to provide guidance to mail order food companies for recommended dates to be used on foods that are mailed to consumers.

Manufacturers provide dating to help consumers decide when food is of best quality. Shelf life studies can be conducted to understand how the product quality and/or safety changes with time. Such studies assess the product's sensory and microbial attributes during the product's estimated shelf life. The shelf life of the product can be adjusted depending upon the results from such studies (NACMCF, 2010).

There are no uniform or universally accepted descriptions used on food labels for open dating in the United States. As a result, there are a wide variety of phrases used on labels to describe quality dates.

Examples of date labeling of meat, eggs or poultry can be found here. https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/food-product-dating/food-product-dating and include:

- A "Best if Used By/Before" indicates when a product will be of best flavor or quality. It is not a purchase or safety date.
- A "Sell-By" date tells the store how long to display the product for sale for inventory management. It is not a safety date.
- A "Use-By" date is the last date recommended for the use of the product while at peak quality. It is not a safety date except for when used on infant formula as described below.

It is recommended that every food item that is mailed be marked with a date and time packaged, mailing date, and a notice to the consumer that the package contains perishable items. If a product's package has been manipulated in any way, the label should be updated to reflect the repackaged date.

Manufacturers may want to provide additional recommendations regarding storage time for their consumers. In this case, it is recommended that the manufacturer provide the recommended storage time and storage method for each particular product. Storage recommendations may need to be modified in order to account for mailing time. Manufacturers may want to include safe food handling instructions to consumers, and recommendations for after the date passes, see for example https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/food-product-dating/food-product-dating .

Part 5. Packaging and mailing to the consumer

Package sanitation and integrity

Any materials used for wrapping and packaging should not be a source of contamination. Packaging and wrapping materials should be stored in the mail order food company such that they are not exposed to contamination. Any wrapping and packaging operations should be carried out in a manner where contamination of the food is prevented. Where pre-packaged foods are mailed to the consumer, integrity of the container's construction should be assured (e.g. no dents in metal cans, no breakage of glass jars). When raw meats are present in the mail order food package, appropriate measures should be taken to prevent leakage and cross-contamination of any other foods or packaging that may be handled by the consumer. Proper packing also serves to prevent chemical and physical contamination of foods. Mail order food companies should be aware of the chemical and physical risks posed by shipping non-food items with food items. Mail order food companies should also be aware that allergens constitute a hazard with a risk that must be managed accordingly. It is recommended that mail order food companies provide a mechanism for the consumer to identify any food allergies during ordering. Care should be taken by the company to ensure unpackaged food items do not come into contact with any potential allergen sources prior to, during, or after packaging the food items for shipment.

Packaging system once product is wrapped

The outer packaging used for mail order foods should be sufficiently robust to prevent damage in transit. The outer packaging may also work as an insulator, keeping cold air in and warm air out. Any damage to the packaging could expose the contents to contamination or to loss of temperature control. Where a more sophisticated package is needed, combined packaging and refrigerant systems are available. Some manufacturers of these systems can supply a validated certificate of temperature control, using in-house calibration facilities via computer software.

Refrigerant/coolant in the package

The need for a refrigerant/coolant and the type/quantity used will depend on a variety of factors, including the outer packaging material, the presence of insulation or dunnage, the food’s initial temperature at time of packing, transit time to consumer and the temperature experienced in transit. The selection of a coolant should not be arbitrary but based on sound scientific principles.

Refrigerant options include, but are not limited to, simple ice contained in plastic, frozen gel packs, plastic packs containing a frozen, ready-made eutectic mixture, and dry ice.

Only potable (drinking) water should be used to make ice packs or constitute gel packs. Frozen gel packs may have a greater ability to maintain a cold temperature than ice alone.

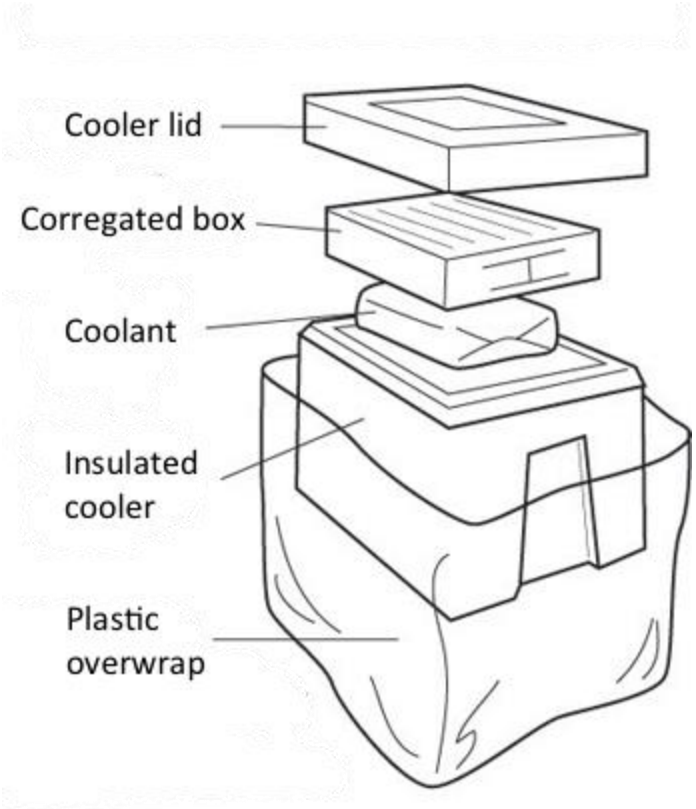
Gel packs often come as a sheet of small, plastic fabric sachets, containing a powder that will swell to form a gel, when submerged in water. The gel sachets can then be frozen, ready for use. When purchasing such products, care must be taken to ensure they are suitable for use with food.

Dry ice may produce colder temperatures than ice or gel packs, but its use requires extreme care for a variety of reasons. First, employees packing the food with dry ice should be adequately trained how to handle dry ice and provided with suitable equipment (e.g. appropriate gloves). Second, its use may be limited by some carriers due to its hazardous nature. Carbon dioxide gas accumulation as the dry ice melts may reach dangerous levels and under certain circumstances may trigger respiratory issues to any drivers or operators exposed. In addition, dry ice can create burns when handled with bare hands. Containers with dry ice should be suitably labeled and declared to the shipping company. In addition, business operators should be aware that additional regulations regarding air shipments containing dry ice exist and must be adhered to at all times. Finally, warnings for consumers related to the safe handling of dry ice should be considered both on dry ice packs and on the website where the food is ordered.

Refrigerant packs will rarely be appropriate for actual cooling of product, but are instead used to maintain the temperature at the time of packaging. Therefore, the food should be cold enough before packing to ensure that proper temperatures are maintained throughout the mailing process, as required by the regulatory authority. Frozen foods must arrive frozen and refrigerated foods must arrive cold. The placement of refrigerant packs or dry ice within the packaging is equally important to ensure all parts of the food are kept at appropriate temperatures throughout the entire mailing process (see the section on validation and verification in Part 4).

Dunnage

Dunnage has different definitions, but in this document, it refers to the extra packing materials used to fill in the empty spaces in the package and which secure and protect the contents during transportation. Use of dunnage may be of critical importance in the shipment of mail order foods because it replaces air in the package, and may help with insulation. The food in a package containing a refrigerant gel pack and air will generally heat up faster than the same food in the same package containing the same quantity of refrigerant, where much of the air is replaced by dunnage (paper, bubble wrap, etc.). Care should be taken not to insulate the food from the refrigerant by incorrect placement of insulation or dunnage.



Example of a packaged food for mail order delivery, adapted from https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/mail-order-food-safety/CT_Index

Destination details

Accurate consumer name and delivery addresses are essential in assuring food safety. Systems should be in place to help ensure the name and address is accurate. Checking the delivery address against one or more databases can help eliminate problems before shipment.

Labeling of transit packaging

There may be an important need to provide advice to the consumer outside the package noting its contents are perishable, especially if the package is sent as a gift or if the recipient is not aware of the contents. Advice regarding prompt refrigeration/storage requirements should always be noted on the inside of the package. The mail order food company should be aware of what labeling their carrier will put on the package, so that it does not obscure any food safety labeling.

General packaging information

A variety of general packaging information can be provided within the package but should be obvious to the consumer and not obscured by other documentation. This general information should include: (a) a use by date for each product, (b) storage instructions for each product, (c)

a clear statement of any satisfaction guarantee and returns policy, (d) allergen warnings, and (e) instructions for use and, if appropriate, additional instructions for preparation and serving. Consumers should be informed of any food products included in the package that may be raw or contain raw ingredients that may pose a risk to the consumer, such as raw milk cheeses, sushi-grade fish intended to be consumed raw, etc.

Choice of carrier and service level

The choice of carrier will depend on a range of factors, including size and weight of packages, availability of service, general reliability, historic performance and commercial viability. Sometimes, specialized delivery services utilizing refrigerated transport may be appropriate.

The mail order food company should keep in mind that mail order food packages are typically treated the same as any other package transported by the chosen carrier and will be stored and transported at the prevailing ambient temperatures. The mail order food company should not expect their package to receive any "special treatment", unless that is part of their agreement with the carrier. The mail order food company should take steps to validate that any promised enhanced level of service is demonstrated, before relying upon it and consequently downgrading any packaging or coolant choices.

To aid in managing food safety, mail order food companies may choose to ship only on certain days of the week.

A non-delivery may occur if the carrier cannot find the delivery address, or if other problems occur. Any process for non-deliveries should be agreed to by the carrier. Some carriers may have specific requirements regarding packaging and labeling related to non-deliveries.

Signature release

Some carriers offer the possibility of signature release (i.e. requiring a signature for delivery). This has the advantage of ensuring that someone is immediately available to take action and refrigerate the food upon receipt. It has the disadvantage of delaying delivery in the case that a signatory is not available.

Consumer concerns

It is recommended that the mail order food company also provide consumers with information about what to do if they are concerned about the safety of the product. In most cases, the appropriate recommendation would be to contact the company for a refund or other action. Consumers also have the right to contact the state or local regulatory agency where the company is located if they have a concern. In such circumstances, mail order food companies can be prepared to respond to any concerns by having standard operating procedures, process records, and other appropriate documentation in hand to demonstrate appropriate practices have been followed.

Handling returned packaging

If the mail order food company has a program to recycle or re-use packaging, an appropriate sanitation program should be in place to manage any allergen or microbial food safety risks that may be present on the reused packaging.

Part 6. Training

This guidance document provides an overview of active managerial control practices for implementing proper food handling. The application of these practices will vary by activity, but a mail order food company operator must, at the very least, ensure adequate food safety training, including food allergy training, for all relevant employees. Food safety is the responsibility of everyone involved in the storing, packing, and distribution of mail order foods. Food handlers must have an appropriate understanding of best food safety practices and control of relevant food safety risks.

Mail order food company operators should ensure:

- That food handlers are trained and supervised in food safety matters commensurate with their work activity. Training involves an overview of food safety principles and instruction on the specific best practices needed for day-to-day operation.
- That those responsible for the development and maintenance of any written food safety programs implemented by the company have the necessary qualifications and experience (e.g. food protection manager certification, etc.).

General principles regarding training

It is a best practice that all training should be given by qualified and competent persons. Businesses should have a plan to identify the training needed for each member of staff, and records that demonstrate this training was completed satisfactorily.

These records likely form part of the evidence the business would use to demonstrate it has a satisfactory food safety management system. Evidence of training in personal hygiene and food safety management may be very important in demonstrating compliance.

Training needs should be assessed on a regular basis. Ongoing training may be necessary as needed (and annually at a minimum). Any training should consider any changes in the business, e.g. changes in the mix of product or packaging methodology which may raise new food safety issues and concerns.

When considering in-house training, there are many established curricula that can be used. These curricula often have documented course instruction notes, which help to ensure consistency. Training records that prove what training was provided should be maintained and may be required by local authorities.

Staff that are not food handlers may also need instruction, supervision or training. These staff may include custodians, sanitation crews, maintenance workers and any other support staff who have access to the operation. These staff should be trained in basic food safety concepts as part of their initial job training.

Supervision and instruction and/or training of food handlers

Mail order food companies who produce their own food products or companies who handle unpackaged foods from other manufacturers must ensure that food handlers receive instruction and/or training in food safety practices appropriate to their food handling duties. The training and/or instruction provided should ensure that food handlers have appropriate knowledge and competence to handle food safely. Mail order food companies should ensure that their employees are trained in accordance with local food code requirements. All food handlers must be supervised to an appropriate level (see further guidance below).

The appropriate food safety knowledge and competencies can be obtained in a number of ways including on-the-job training, self-study through recognized guidance materials, and attending formal training courses or through prior experience.

Appropriate arrangements should be made for persons whose first language is not English and/or persons with learning or literacy difficulties.

The following list highlights the basics of what all food handlers need to know:

- No bare hand contact with RTE foods.
- Practice proper handwashing. Employees should wash their hands thoroughly after touching bare human body parts, after using the toilet room, after caring for or handling service animals or aquatic animals, after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking, after handling soiled equipment or utensils, during food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks, when switching between working with raw food and working with RTE food, or before donning gloves to initiate a task that involves working with food.
- Tell their supervisor (before commencing work) if they show any of the following symptoms: vomiting, diarrhea, jaundice, sore throat with fever, lesion or infected wounds.
- Notify their supervisor if they've been diagnosed with a foodborne illness.
- Ensure cuts and sores are covered with a waterproof, high visibility dressing, and covered with a disposable glove.
- No eating, drinking, smoking, coughing, sneezing, blowing the nose, scratching the head, placing fingers in or around the nose and mouth, around food or packing material.
- Follow all supervisor food safety instructions.
- Keep perishable food refrigerated at 5 °C (41°F) or below.
- Segregate raw and RTE foods.
- Wear clean outer clothing.

- Workplaces and any food contact surfaces should be clean and sanitized.
- Report sightings of pest activity.
- Inform supervisors of any uncontrolled foodborne illness risk factors.
- Practice good inventory management to ensure product rotation (FIFO).

All staff should be properly supervised and instructed to ensure that they work in sanitary conditions and in accordance with proper food safety procedures. Even if staff has received instruction and/or training, supervision to ensure compliance by the food handler is needed. Supervision is typically performed by someone designated as the Person In Charge (PIC). Where an operation employs only one or two people, supervision may not be applicable, however the PIC should always be appropriately trained. Details regarding the duties of the PIC can be found in Section 2-103.11 Person in Charge and Annex 3, Section 2-103.11 of FDA Model Food Code.

The FDA Model Food Code also recommends a Certified Food Protection Manager (CFPM). A CFPM is an individual who has demonstrated (by means of passing a food safety certification examination from an accredited certifying organization) that he/she has the knowledge, skills and abilities required to protect the public from foodborne illness. Duties of such persons could include but are not necessarily limited to:

- Identifying hazards in the day-to-day manufacturing operation of the mail order food company.
- Development or implementation of specific policies, procedures or standards aimed at preventing foodborne illness.
- Coordinating training, supervision or direction of food preparation activities, and taking corrective action as needed to protect the health of the consumer.
- Completing in-house self-inspection of daily operations on a periodic basis to see that policies and procedures concerning food safety are being followed.
- Achieving active managerial control in implementing proactive systems for preventing foodborne illness.

Training in the application of HACCP principles

Although retail HACCP is not a legal requirement in the United States, HACCP principles can be applied to ensure food safety within the mail order food company. The regulatory agency having jurisdiction over the mail order food company may specify the type of training required, and should be contacted to determine if such training is required.

Supervisors of the mail order food company should ensure that those within the business responsible for developing and maintaining the HACCP-based food safety management procedures or standard operating procedures are appropriately trained.

As in the case of food handler training or instruction, mail order food companies are responsible for determining how training in HACCP principles or standard operating procedures is achieved. The appropriate knowledge and competencies can be obtained in a

number of ways including on-the-job training, self-study through industry recognized guidance materials, and attendance at formal training courses or prior experience.

Part 7. Appendices

Appendix A: Food regulation overview, labeling and recalls

Regulatory overview

Federal, state, and local agencies oversee the regulation of retail and manufactured food products. Most products sold in interstate commerce, or across state lines, will be regulated by both state or local and federal food regulatory agencies, with a few state-specific exceptions. Most products sold in intrastate commerce, or made and sold within the same state, will be regulated by state or local food regulatory agencies. Most facilities that handle food are licensed in some manner. Mail order food companies should contact the agency that issues their license or permit if they have questions about the food safety regulations that apply to their operation. If a mail order food company is unsure who issues their license or permit or if one is required at all, the mail order food company should contact their state or local health department. Health departments can typically assist or direct the mail order food company to the appropriate agency. Mail order food companies can also follow this link for state health department information: https://www.foodsafety.gov/about/state/index.html.

For additional information regarding the food products that federal agencies oversee, follow the links provided below:

Food and Drug Administration – What does FDA regulate?
https://www.fda.gov/aboutfda/transparency/basics/ucm194879.htm

U.S. Department of Agriculture Food Safety Inspection Service
https://www.fsis.usda.gov/wps/portal/fsis/home

Food laws

There are many laws which provide the basic framework for ensuring safety of foods in the US, including mail order foods. These laws include but are not limited to the Food Drug and Cosmetic Act (FDCA), the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA). These laws prohibit the sale or distribution of adulterated foods. Foods can be deemed adulterated for many reasons including if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

The FMIA specifically prohibits adulteration during transportation, where adulteration means any act while being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such articles to be adulterated or misbranded.

Therefore, mail order foods must always be transported in a way that minimizes the risk of contamination and potential adulteration of the food.

Food regulations

The Food Safety Modernization Act provides multiple rules and guidance that may pertain to mail order food companies. Some of these federal regulations address sanitary situations that apply to transportation of foods. A link is provided below for reference to these rules and guidance and any questions related to their applicability to a mail order company's operation should be directed to the FDA. Information regarding how to contact FDA can be found at https://www.fda.gov/Food/ResourcesForYou/ucm334249.htm

For further information on Rules and Guidance for Industry related to the FDA Food Safety and Modernization Act (FSMA) to go:
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm

The USDA FSIS Sanitation Rules address shipping as follows:

> 9 CFR §416.4 Sanitary operations.
>
> (d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

FDA's Model Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service. Most state and local codes are based on the FDA Model Food Code that provides rules which may be relevant to packing and shipping of mail order foods. The FDA code can be obtained here https://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/.

USDA has various regulations that apply to transportation of meat and poultry, but also provides the following information to consumers on Mail Order Food Safety https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/mail-order-food-safety/ to help consumers determine if their perishable foods have been handled properly:

- Make sure the company sends perishable items, like meat or poultry, cold or frozen and packed with a cold source. Items should be packed in an appropriate container to ensure temperature control and protect the food(s) from contamination.
- The food should be mailed as planned, using mailing plans that have been validated to deliver appropriate temperature control. Make sure perishable items and the outer package are labeled appropriately (e.g. "keep refrigerated") to alert the recipient as to proper handling.
- The company should inform their consumers on how to handle foods on receipt. They may wish to include information on how to measure product temperature and what to do if foods are received outside the delivery window, at unacceptable temperatures, or in a damaged condition.

- The company should be aware of situations where a consumer is ordering food for another individual (e.g. as a gift), and should develop and implement a notification system appropriate for these situations.

Labeling

As part of their obligations to comply with general legal requirements, proprietors of mail order food companies need to ensure that the labeling of food is correct and not misleading and that the food's chemical composition and any materials and articles that come into contact with the food are not harmful to health.

Where a mail order food company receives pre-packed foods (i.e. already in their primary packaging), such as canned, vacuum packed or pouch packed goods from another company, the food should be correctly labelled by the other business. Depending on the product, the labeling required can be extensive. However, where the proprietor of a mail order food company operation repackages individual items, they may have more limiting mandatory labeling to perform and should take care to ensure the requirements have been satisfied.

If a mail order food company wishes to make a claim concerning its products, whether these claims relate to the origin, species or nature of the product, e.g. Alaskan salmon, vegan or organic, it would be advisable to take steps to substantiate these claims.

Recalls for mail order food companies

A detailed discussion of the complexities of food recalls is beyond the scope of this document. However, an awareness of, and preparation for recalls is an important part of a food safety plan for all mail order food companies. Any mail order food company should have four key aspects of their food safety system in place that relates to recalls:

- The mail order food company should have a means for tracking all recalls that are relevant to their business. The company should not rely upon their suppliers to inform them about the need for a recall, but should actively seek out relevant information.
- The company should have a means to stop online sales once they learn of a relevant recall.
- The company should have a method to notify any consumers who have purchased a recalled product, and inform them that the product they purchased has been recalled.
- Finally, the company should have a system to manage recalled inventory, to ensure that any recalled product is appropriately tracked, controlled, and ultimately destroyed or reconditioned, and does not re-enter commerce.

More information regarding recalls is available on both FDA and USDA FSIS websites. A brief description of that information follows below.

FDA recalls

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under their statutory authority. FDA divides recalls into four categories:

- Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- Market withdrawal: when a product has a minor violation that would not be subject to FDA legal action it may be withdrawn from commerce. The firm removes the product from the market or corrects the violation.

For additional recall information, see recall Regulations in 21 CFR Part 7
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=7&showFR=1

USDA FSIS recalls

FSIS recalls are initiated by the manufacturer or distributor of the meat or poultry product, sometimes at the request of FSIS. All FSIS recalls are voluntary. However, if a company refuses to recall its products, then FSIS has the legal authority to detain and seize any products that are in commerce.

FSIS notifies the public through a Recall Release for Class I and Class II recalls, and issues a Recall Notification Report (RNR) for Class III recall issues. The definitions for FSIS Class I, II and III recalls are slightly different than for FDA products, and are summarized below:

- Class I: involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death.
- Class II: involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food.
- Class III: involves a situation in which eating the food will not cause adverse health consequences.

For more USDA FSIS information on recalls
https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts

Appendix B: Trading standards and imported food issues

Under the U.S. Federal Food, Drug and Cosmetic Act, importers and brokers of food products intended for introduction into U.S. interstate commerce are responsible for ensuring that the products are safe, sanitary and labeled according to U.S. requirements. Both imported and domestically-produced foods must meet the same legal requirements in the United States. FDA is not authorized under the law to approve, certify, license, or otherwise sanction individual food importers, product labels, or shipments. Importers can import foods into the United States without prior sanction by FDA, as long as the facilities that produce, store, or otherwise handle the products are registered with FDA, and prior notice of incoming shipments is provided to FDA. Imported food products are subject to FDA inspection when offered for import at U.S. ports-of-entry. FDA may detain shipments of products offered for import if the shipments are found not to be in compliance with U.S. requirements. For an overview of the U.S. Import Program, please see:
https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/default.htm

Food imported into the United States directly to consumers by international mail is subject to prior notice requirements based on the Prior Notice Interim Final Rule. The prior notice may be submitted more than five calendar days before the anticipated date of arrival; however, the prior notice must be submitted before the food is sent to the U.S. The Prior Notice Confirmation Number must accompany the article of food and must appear on the Customs Declaration that accompanies the package. For further information about sending food to consumers through international mail, visit the following FDA link:
https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm082154.htm

The FDA Food Safety Modernization Act gives FDA new tools and authorities to make certain imported foods meet the same safety standards as foods produced in the U.S. The following link outlines FDA's key new import authorities and mandates:
https://www.fda.gov/food/guidanceregulation/fsma/ucm257980.htm

The USDA Food Safety and Inspection Service (FSIS) is responsible for ensuring that domestic and imported meat, poultry, and egg products are safe, wholesome, and accurately labeled.

Foreign countries that export meat, poultry, and egg products to the United States are required to establish and maintain inspection systems that are equivalent to those of the United States. The USDA FSIS provides detailed guidance on steps to ensure meat, poultry, and egg products are imported in compliance with the applicable statutes and regulations of the United States:
https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/fsis-import-procedures-for-meat-poultry-and-egg-products/fsis-import-procedures