



Best Practice for Direct to Consumer Sales

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I. Introduction

Preparers of food sold direct to consumer (D2C) must comply with the applicable federal, state, and/or local food safety laws and regulations involved in a particular food delivery model, and these may vary depending on the types of foods being produced and delivered. It is important that all segments of the food supply chain work together to ensure the safety of the finished products. This requires an understanding of potential food safety risks and controls needed throughout the system. The scope of this document is focused on food safety best practices.

II. VOCABULARY

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.

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

HACCP: Hazard Analysis and Critical Point system is a preventive approach to controlling food safety hazards.

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.

Staging: time between preparation and pick-up or delivery.

Tamper evident: Tamper-evident describes a device or process that makes unauthorized access to the protected object easily detected. Seals, markings, or other techniques may be tamper indicating. Tampering involves the deliberate altering or adulteration of a product or a package.

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.

Allergen: Substance that causes an allergic reaction or a damaging immune response. In the U.S., the following nine major food allergens are milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soybean, and sesame

Foreign Material – physical compound that should not be in food, and can be classified as adulterants because they are unfit for human consumption, may contain poisonous or deleterious substances, and render the products unwholesome or injurious to health.

Lot – a defined/specified amount of product that is identified based on factors such as production dates and times, clean-up or separation from other products, raw material sources, production lines, etc. Lot identification connects and or separates products from each other.

Lotting system – the mechanism/process used by the establishment to define a lot.

Consumer – the person purchasing the products for his/her use.

Point of sale – the place at which the products are retailed.

Delivery – the process of transporting the product from the processing facility to the consumer.

In person sale – the individual purchasing the product physically visits the location where the product is being sold.

Principal display panel – the part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions or display for sale.

Distribution Center – storage location for products that are shipped from one business to another business

Fulfillment Center – picks, packs and ships products directly to consumers

Dunnage – Extra packing materials used to fill in the empty spaces in the package and which secure and protect the contents during transportation.

Label – all labels and other written, printed, or graphic matter upon any product or any of its containers or wrappers, or accompanying the product.

Shipping container – the outside container (box, bag barrel, crate or other receptacle) containing or wholly or partly enclosing any product packed in one or more immediate containers.

Immediate container – the receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

III. DIRECT TO CONSUMER PURCHASING SCENARIOS

A. IN PERSON SALE DIRECT TO CONSUMER

1. *On-site manufacturing location*
2. *Off-site sales location (farmers market)*
3. *Mail order*

B. DELIVERY FROM RETAIL STORE TO CONSUMERS

1. *Store shop, store delivery*
2. *Store shop, customer pickup*
3. *Store shop, 3rd party delivery*
4. *3rd party shop, 3rd party delivery * outside the scope of this document **

C. RESTAURANT RTE/RTH FOOD DELIVERY DIRECT TO CUSTOMERS

1. *Company Owned Fleet Delivery*
2. *Customer pickup*
3. *3rd party delivery*
4. *Mail order*
5. *Restaurant to retail to consumer *outside the scope of this document**

D. SHIP TO CUSTOMER FROM:

1. *Manufacturing*
2. *Fulfillment*
3. *Distribution Center*

IV. PRODUCT TYPE

Product risks based upon variety of types of products should be considered. Product evaluation should occur every time you change or modify product profile.

A. RAW/COOKED

Food safety hazards, potential controls, handling practices along the chain must be addressed to ensure that raw products do not contaminate cooked, ready-to-eat products during production, packaging, storing, or delivery.

B. FRESH/FROZEN -

Food safety hazards, potential controls, handling practices along the chain must be addressed to ensure that proper temperatures are maintained for fresh and/or frozen products to prevent temperature abuse and potential growth of biological hazards.

C. SINGLE INGREDIENT/MULTI-INGREDIENT

Food safety hazard and controls for should be identified for single and multi-ingredient products to prevent contamination throughout the process.

V. PACKAGING/LABELING

Appropriate packaging materials and labels shall be selected or considered based on the temperature of shipment. Labels should be constructed and adhered to the package so that identity is not lost if product has condensation, thaws or has a change in temperature.

Packaging should be chosen so that cross contamination does not occur. For example, if a product will be shipped where product will thaw and will exude a purge or water loss that this exudation is contained within the product primary package.

Potential risk should be considered for eliminating:

- Foreign material
- Mislabeling
- Misbranding
- Allergen (cross contact/mislabeling)

A. BASIC REQUIREMENTS (USDA REQUIREMENTS)

There are eight requirements for product labels according to USDA-FSIS:

1. Product name
2. Inspection legend with establishment number
3. Handling statement
 - FSIS approved statements:
 - Keep Refrigerated.
 - Keep Frozen.
 - Perishable, Keep Refrigerated.
 - Previously handled frozen for your protection. Refreeze or Keep Refrigerated
4. Net weight statement
5. Ingredient statement (if more than a single ingredient item)
 - Ingredient statement should be accurate and reflective of all components of the product.
6. Address line (this could include the address of the manufacturer, packer or distributor)
7. Nutrition facts
8. Safe handling instructions – required for raw or partially cooked items, not ready to eat products

Visit [FSIS Compliance Guidance for Label Approval](#) for more information on labeling requirements.

B. SPECIAL STATEMENTS AND CLAIMS

1. *Allergens*

There are specific food items that people are sensitive or intolerant to, specifically a group of food products that are called the “big 9” allergens. The allergens include:

1. Wheat
2. Crustaceans
3. Eggs

4. Fish
5. Peanuts
6. Milk
7. Tree nuts
8. Soybeans
9. Sesame

Visit the [Guidance for Allergen Control in Meat Establishments](#) for additional information.

2. *Sensitive ingredients – gluten, MSG, etc.*
3. *Mechanically tenderized*

C. ADDITIONAL INFORMATION TO CONSUMERS

Safe handling and preparation guidelines should be included for all products. Clear instructions for consumer to follow in response to suspected tampering or temperature abuse should be included as well.

For additional information surrounding consumer guidance see, [Prep yourself | Partnership for Food Safety Education \(fightbac.org\)](#).

VI. DISTRIBUTION

A. PACKAGING

Packaging should be suitable for the intended products, volume of contents, and delivery scenario. Tamper evident packaging should be utilized.

The [Guidance Document for Mail Order Food Companies](#) has relevant information for mail order packaging considerations.

B. TEMPERATURE CONTROL

1. *Cold Chain Maintenance – refrigeration & frozen*
 - Time and temperature parameters for delivery/shipping should be evaluated based on products included to ensure food safety.
 - Temperature monitoring should be accessible for easy verification (eg. refrigerated trailer data downloads, remote monitoring devices, or other indicator technologies)
 - The original product state (refrigerated or frozen) should be maintained when products are picked and staged for shipment or pick up.
 - Considerations related to shipping container type, coolant type and volume used should include the expected duration of time in transit, as well as the use of contactless drop off, customer signature of receipt, wrong address, or cold chain delays, which may extend the expected duration of time in transit.
2. *Monitoring Temperature Through Distribution*
 - When shipping internally between entities the use of readable temperature recording devices can be utilized. These devices are widely available with options for reuse or one

time use. Temperatures can be monitored in the range of –20F to 100F which is sufficient for refrigerated or frozen shipments. Most devices in the marketplace have the capability of recording temperature on an established interval and have the accuracy of +/- 2 F.

- One time use temperature monitors can also be used. These devices can be used to determine if the environment exceeded a specific temperature. These temperature monitoring devices basically turn colors once the temperature exceeds the range of the device. Select devices that have a maximum temperature of 40F for Fresh products and 10 F for frozen products. While these temperatures are above the ideal range the range is still an acceptable level to maintain the quality of the product.

3. *Conduct a shipping validation which would include:*

- Develop and verify specifications, processes, systems, and components used in your shipping process. Seasonal variations should be considered.
- Process packages under controlled temperatures to determine if the specifications established maintain the temperature for the amount of time expected for delivery.
- Develop justifiable test methods and acceptance criteria.
- Ongoing monitoring and/or periodic evaluation is needed to continuously improve your process
- Change control process must be identified and followed.

C. FSMA FINAL RULE ON SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD

For dual jurisdiction products, reference [FSMA Final Rule on Sanitary Transportation of Human and Animal Food](#). The rule establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food. The rule provides additional guidance for:

- Cold chain maintenance
- Cleaning and sanitation
- Integrated pest management
- Traceability/recall/return management
- Protection of food
- Training and Supervision
- Documentation and records

VII. TRACEABILITY CONSIDERATIONS

Inbound raw materials, including ingredients, protein, contact packaging used to prepare finished goods should have lot coding system that is documented and preserved ([Sampling, Lotting, and Sample Analysis](#)).

Lot information of finished goods into a parcel destined for a consumer should be captured and preserved along with name, address, contact information of consumer.

Traceability exercises to assess ability to recover information and identify consumers affected should be practiced (USDA requirements for written recall process, FDA, industry Guidance for recalls, FSMA proposed rule for traceability).

The purchaser and recipient (ship to, pick up, etc.) may not always be the same person/address/contact information.

VIII. RECALL PLAN/SYSTEM

It is important to have a recall plan and perform recall effectiveness checks/mock recall. Refer to [How to develop a meat and poultry product recall plan](#) or [Guidance for Retailers Product Recall](#) for more information.

IX. VALIDATION AND VERIFICATION OF PROCESS CONTROLS

It is critical to validate all components above as well as verify processes are working as outlined once production and distribution happens. The [Guidance Document for Mail Order Food Companies](#) provides some guidance in this area but each company should develop both related to their own process.

Validation of controls may be needed for processes applied before and during production, display or storage, transportation, and end-user handling and preparation. This may require supporting documents for decisions, resources, or regulatory information to ensure proper handling throughout the D2C chain for food safety.

X. FOOD DEFENSE

A food defense plan is a tool that allows an establishment to identify steps to protect the food and food process from intentional harm. For D2C programs, the food defense plan should address supplier approval, the production/processing, storage/distribution centers, and shipping/delivery sources. Visit FSIS's [Food Defense Mitigation Tool](#) or FDA's [Food Defense Tools](#) for more information.

This document was developed by members of the Beef Industry Food Safety Council. Best Practice documents are ever evolving, and as changes or new information becomes available, these documents will be reviewed and updated. Questions or suggestions are welcome and should be addressed to BIFSCO at bifSCO@beef.org.