Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery

Prepared by the
Direct to Consumer Delivery Committee
2018-2020 Conference for Food Protection

Don Schaffner, Chair
Albert Espinoza, Vice Chair
Anthony Auffray
Nancy Beyer
Christina Bongo-Box
Robert Brown
Catherine Feeney
Caroline Friel
Joe Graham
Cris Hernandez
Rosalind LaFleur
Valerie Madamba, Subcommittee Chair
Corey Millwood
Joseph Navin
Travis Patton
Jim Rogers
Lily Yang
Jessica Zetlau, Subcommittee Chair

Federal consultants and alternates:
Melanie Abley
Susan Hammons
Jessica Otto
Donna Wanucha

Council III chair and vice-chair:
Keith Jackson
Christine Applewhite

At-large, non-voting members:
Christina Ams
Thomas Arbizu
Joshua Ball
Callie Bleckner
Jeffrey Clark
Alicia Collins
Matt Colson
Michelle Cox-Horton
Liz Duffy
Adam Friedlander
Kathryn Heil
Becki Holmes
Sharon Humphries
Sarah Kantrowitz
Helen Kor
Nidal Khatib
Aimee Lee
Michael Luczynski
Todd Mers
Ashley Miller
Elaine Money
Eric Moore
Jaymin Patel
Brandy Sheehan
Ellen Thomas
Scott Vinson
Dilshika Wijesekera
Linda Zaziski

based on an earlier draft from
Mail Order Foods Committee
2016-2018 Conference for Food Protection

Christine Applewhite, Chair
Christina Bongo-Box, Vice-Chair
Anthony Auffray
Mitzi Baum
Blanca Caballero
Andrew Harris
Deborah Marlow
Jennifer Reyes
Don Schaffner
Ellen Thomas
Lisa Weddig
Kelli Whiting
John Zimmermann

Federal consultants and alternates:

Melanie Abley
Kristina Barlow
Mary Cartagena
Evelyne Mbandi
Jessica Otto

At-large, non-voting members:

Ashley Hallowell
Aimee Lee
Clyde Manuel
Mark Moretz
Alli Pearson

Council III chair and vice-chair:

Davene Sarrocco-Smith
Keith Jackson

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1. Preface

Council III of the 2018 Conference for Food Protection (CFP) formed the Direct to Consumer Delivery Committee, in response to Issue 2018-III-006, which was charged to:

1. Identify current recommended practices and existing guidance documents that relate to shipment directly to a consumer of perishable food items and for the safe delivery of food by Third Party Delivery Services (TPDS) entities.

2. Revise the Guidance Document for Mail Order Food Companies that includes recommended 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. Current guidance document to be revised to include food safety training for the TPDS entities, and information on all food delivery practices from food production, distribution, or retail food service facilities.

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 2020 Biennial Meeting of the Conference for Food Protection.

This guidance replaces the 2016 “Guidance Document for Mail Order Food Companies”, which was produced by the former Mail Order Food Safety Committee in response to Issue 2016-III-037.

The 2016 Guidance was informed by “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.”

2. Introduction and Scope

This guidance document provides food safety best practices for managing or performing Direct to Consumer (DTC) or third-party delivery (TPD) services. This document includes parameters critical to preventive controls, mechanisms to assess risk, validation and verification practices, recommendations for proper packaging, temperature control, 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 transported.

The methods by which foods reach the final consumer can vary significantly, and this guidance is not intended to provide a "one-size-fits-all" approach. This guidance aims to review some of the essential parameters that any company should consider in providing safe foods to the consumer. Companies should research, understand, and test the methods best suited to their specific operation.

This guidance recommends best practices and provides references that may help in this process. The use of this guidance is voluntary. It is not a regulatory document. Food companies, including food manufacturers and food establishments where food is held or prepared for DTC or TPD are subject to applicable federal, state and local food safety statutes and regulations. It is important that DTC and TDP companies understand all legal and regulatory requirements, as well as industry guidelines, governing the safety of food throughout production and distribution.

This guide does not specifically address (a) the delivery of foods intended for immediate consumption from food establishments where the delivery is under the control of the food establishment who prepared and delivered the food by the food establishment's employee, since these companies are already regulated by state and local codes or (b) export requirements, tariffs or customs aspects of international deliveries. Although not covered by this document, the information provided here may contain useful advice for delivery of foods intended for immediate consumption from restaurants where the delivery is under the control of the restaurant who prepared the food and delivered by a restaurant employee.

3. 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.

Best Practices: Those practices that represent the "state of the art" or current best approaches of assuring food safety and quality based on state of the science and technology.

Broker: A food broker is an independent sales agent that works in negotiating sales for food manufacturers. Food brokers work for both manufacturers and buyers of food as they help "broker" deals to sell food products to a variety of buyers.

Common Carrier: A person or company that transports goods for any person or company.

Coolant: A coolant (also called a refrigerant) is defined in this document as a time-limited source of temperature reduction, such as an ice or gel pack. Coolants are often better used to maintain cold food at temperature rather than bring warm food down to a cold temperature.

Direct to Consumer (DTC) Food Delivery: Food that may be ordered through any non-face-to-face communication (e.g., via mail, phone, fax, email, or internet) and delivered to consumers through various channels (e.g., mail, common carrier, internal company logistics). DTC Food Delivery companies are generally not limited by specific geographic radii, unlike third-party delivery services which are defined below.

Direct to Consumer (DTC) Food Delivery Company: A business organized to promote, receive, prepare, fulfil, and transport orders of food directly to consumers. This term reflects an evolution of the term "Mail Order" used in prior versions of this document.

Feed: The Food, Drug, & Cosmetics Act (FD&C) defines feed as an article which is intended for use for food for animals other than man. Feed is intended for use as a substantial source of nutrients in the diet of the animal and is not limited to a mixture intended to be the sole ration of the animal. Feed safety (and thus pet food safety) is not specifically within the scope of the charge addressed by this document.

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 Deliverer: A person or unmanned transportation device (e.g. drone, robot, driverless car, etc.) which receives a food order that was placed via a Food Ordering Platform, retrieves the food order from a Food Establishment, and transports the order to the consumer's designated location.

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 Food and Drug Administration's (FDA) model 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 (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 delivery service that is provided by common carriers.

Food for Home Preparation: Food that is delivered to a consumer where the consumer is expected to prepare/cook the food**.**

Food for Immediate Consumption: Prepared food that is delivered to a consumer where the expectation is that the food is going to be consumed without extensive preparation and consumed shortly after arrival.

Food for Later Consumption: Food that is delivered to a consumer where the expectation is that the food is going to be consumed without extensive preparation and may be stored for some time and/or consumed shortly after arrival.

Food Ordering Platform: An online marketplace that connects food establishments with consumers and food deliverers. The Food Ordering Platform does not manufacture or otherwise prepare the food, which is delivered, but instead facilitates the delivery of those items.

Food Safety Plan: This document uses the phrase food safety plan in a generic sense. This is not to be confused with a food safety plan that is required for compliance with the Food Safety Modernization Act (FSMA). The business entities discussed in this document may or may not be subject to compliance with FSMA.

Food Shopper: A person who receives an order that was placed on a Food Ordering Platform, selects food and/or non-food products from a Food Establishment on behalf of a consumer, bags/boxes the products for shipment/delivery, and places the bagged/boxed products in a staging area for future delivery to the consumer. A food shopper may also be a food deliverer and transport the order to the consumer's designated location.

Food: As noted in the FDA model Food Code and Code of Federal Regulations, "Food" means a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption or chewing gum.

HACCP: Hazard analysis and critical control points is a systematic preventive approach to manage risks from biological, chemical, and physical hazards in food processing or preparation. In some (but not all) cases HACCP is part of a regulatory framework (i.e. FDA Juice HACCP).

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

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

Monitoring: Defined as conducting a planned sequence of observations or measurements of control parameters to assess whether a process is under control.

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

Pathogen: A microorganism of public health significance.

Perishable Foods: Foods that are required by law to remain at specific refrigerated food temperatures for product safety. See definition below for time/temperature control for safety foods or TCS foods. They have been historically called potentially hazardous foods (PHF). Guidance on applicable food products can be found later in this document.

Preventive Controls: Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would use to minimize or prevent the hazards identified under the hazard analysis. These controls should be consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Provisioning System: The means by which a third-party delivery service is connected with a food establishment.

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

Records: Documentation of actions taken or parameters recorded. Records may be hard copy or electronic in form. The appropriate record form may be impacted by the regulatory jurisdiction. Record retentions requirements are often related to the shelf life of the food and may also be subject to regulatory requirements.

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

Risk Control Plan: A risk control plan is a systematic approach to identify and manage food safety risks.

Risk: The likelihood that an adverse health effect will occur within a population as a result of a hazard in a 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: Period of time after preparation and before pickup. May or may not include hot or cold holding.

Standard Operating Procedures (SOP): This term refers to standardized written procedures for performing various tasks. When used in a food safety context SOP's are designed to ensure food safety by following appropriate practices each time a given task is performed.

Third-Party Delivery Service: A food delivery where a consumer uses a Food Ordering Platform to place an order from a selection of Food Establishments and receives delivery of that order from a Food Deliverer. Third party delivery service is generally defined as offering consumers the option to place an order from Food Establishments within a defined geographic radius.

Time/Temperature Control for Safety (TCS) Food: A food that requires 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.

4. Foundational concepts

A. Regulatory Requirements

There are requirements in federal, state and local laws and regulations that are relevant to the transportation and delivery of food. For example, state, territorial and local regulations modeled after the FDA model 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. For TCS foods prepared for hot holding, the FDA model Food Code establishes a minimum storage and display temperature of 57°C (135°F). Other temperature limits may be appropriate for foods that do not require temperature control for safety but that are kept cold to preserve quality and limit the growth of spoilage organisms.

While retail food establishments are generally governed by local regulations, food processing and manufacturing companies are also subject to a variety of food safety authorities, depending on the nature of their operations. For example, food facilities that are required to register with FDA must generally comply with the Preventive Controls for Human Food Rule under the FDA Food Safety Modernization Act (FSMA) as well as applicable Current Good Manufacturing Practices (CGMPs). DTC food companies subject to this rule are required to implement a food safety plan that addresses hazards and risk-based preventive controls for minimizing or preventing those hazards.

Any approach to controlling risk in DTC or TPD foods should be consistent with the federal, state, and/or local food safety laws and regulations that may apply to the various organizations involved in a particular food delivery model. Further resources regarding potentially applicable laws and regulations are provided in Appendix A.

B. Risk Management Overview

Identifying, assessing, and controlling risk in DTC or TPD foods

DTC or TPD models can be complex and often involve several parties in the production and distribution chain. To ensure that food is delivered safely to the end consumer, the parties involved should work together to identify when food safety risks are reasonably likely to arise, what measures are needed to control those risks, and who is responsible for implementing those measures.

We encourage organizations involved in DTC and TPD to manage risk using a HACCP-based approach that accounts for all steps of a business model, including storage; packaging; repackaging; labeling; preparation; physical retail sale; selection (such as by a grocery delivery

service); transport and delivery by employees, independent contractors, third parties, or others; and consumer communication. The approach should reflect food safety parameters and controls for risks that may arise throughout the DTC or TPD processes. Delivery parameters may include delivery time, travel distance, number of orders per delivery, and take into consideration unplanned events such as gas, flat tires, and authorized breaks.

The various parties involved in a DTC or TPD operation may determine that existing approaches, such as a HACCP plan or a Food Safety Plan under the FSMA Preventive Controls Rule, are adequate to control risk. Alternatively, some parties may determine that they need to adopt new protocols for implementing the risk-control measures agreed upon by the various parties. Regardless, the parties should clearly communicate the necessary risk-control measures and agree upon who will implement each (see Section 5.H for further discussion).

Validation and verification

Validation and verification are two critical but distinct elements of any food safety program. Validation involves obtaining and evaluating scientific and technical evidence that relevant risks have been detected and controlled. A validated control measure or a combination of control measures when properly implemented will effectively control identified risks. Examples of validation activities include identifying food safety parameters in scientific journals and/or regulatory guidance or rules and conducting studies using the company's products and packaging. A company should conduct validation before launching operations. Verification occurs after validation has been conducted and is intended to demonstrate whether validated measures are working as intended and are being effectively carried out. Validation is conducted before operations begin and perhaps annually thereafter. Verification should be conducted periodically as operations continue. Verification will occur more frequently than validation. Both validation and verification records should be maintained according to any applicable regulatory requirements.

Validation. Any business that intends to engage in DTC or TPD operations should identify and validate controls for the food safety risks it has identified. A company may perform validation activities in-house or may choose to have validation conducted by a reputable external entity. Given that multiple parties may be involved in processing, holding, handling, or transporting DTC or TPD food, these parties should work together to determine that end-to-end risk-control requirements are met. Risk-control requirements may include inputs that will enable control (e.g. thickness and insulative ability delivery packaging, number and positioning of gel packs, gel melting point) as well as outputs that demonstrate control (e.g. product inner temperature below 41°F upon delivery).

Validation data for DTC or TPD foods should be obtained both before launch and any time an essential component of the delivery model is modified, such as when the delivery area is expanded, or a packaging element is changed. Deliveries should not begin until the validation demonstrates that identified risks will be adequately controlled and deliveries do not exceed the validation parameters. Upon identification of chill chain systemic gaps or in the event previous validation records are no longer available, the company should perform a validation or re-validation as soon as possible.

Temperature controls may be the most important element in DTC or TPD to validate, but validation may also need to be conducted for other food safety measures. Companies should identify any other food safety risks that should be controlled in their operations and should determine the appropriate measures for controlling such risks.

Verification. Verification activities may include implementing and reviewing logs or checklists to ensure that validated food safety measures are implemented as required or conducting periodic internal or external audits of the company's food safety program. When verification shows that risk-control measures are not being adequately carried out, corrective actions should be identified and implemented. Corrective actions will vary and should be tailored to the identified deviation; examples may include conducting additional training, revising existing procedures, or developing new protocols. The parties involved in a DTC or TPD food operations should establish clear responsibilities for identifying and implementing corrective actions. Please refer to Section 5.H for a detailed discussion of best practices, including monitoring and strategies for managing noncompliance.

Risk Management Resources

Both internal and/or external resources can be useful in managing risk, and each has its own specific attributes.

Internal resources. Dedicated internal staff provide a company with the flexibility to adjust food safety programs, conduct self-assessments, respond to food safety complaints/inquiries, and respond to emergencies (e.g., equipment failures, severe weather events potentially impacting transportation and product safety).

External resources. Employing external resources, such as a third-party auditing firm to assess food safety risks, can offer a number of benefits. Subject matter experts with food safety credentials and experience can offer added credibility. Professional evaluators dedicated to evaluating food safety risks typically can have specialized training in inspection techniques and root cause investigations. External experts can offer objectivity during assessments and consultations. External experts can offer an enhanced ability to collect data, generate insights, and make recommendations for improved food safety practices. Such experts can serve as important resources during emergencies (e.g., natural disasters, weather events, recalls, and outbreaks) when existing internal resources are saturated. External experts may offer services that are available more broadly, either locally, throughout the country or globally. Finally, external resources may supplement internal resources by helping with program design and updates to educational materials and SOPs.

5. Direct to Consumer guidance

A. Considerations Prior to Delivery

A DTC food delivery company should implement procedures to ensure that food is produced under safe and sanitary conditions and address the food safety risks relevant to its operations. A starting place for this is to ensure the food is made by a company registered and/or approved by the appropriate regulatory authority. Company may also verify (with a documentation review or a physical audit performed internally or by a third party) additional qualifications such as implementation of Good Manufacturing Practices and HACCP. While this guidance focuses primarily on food safety considerations specific to DTC food delivery, a company should be familiar with general best practices and requirements relevant to receiving, storage, processing, and holding foods intended for delivery. For example, any DTC delivery food safety program must meet the regulatory requirements applicable to the company's operations, e.g., the state and local food codes, CGMPs, or the Preventive Controls for Human Food Rule under FSMA. Certain foods, including eggs, juice, milk products, meat, poultry, seafood, and low-acid canned foods, may be subject to specific regulatory requirements. Further resources are provided in Appendix A.

Consumer information and notifications. Companies should have systems in place to help ensure consumer names and delivery addresses are accurate because delivery delays may impact food safety. Depending on their product(s) and delivery model, companies may consider providing consumers with guidance on handling deliveries (e.g., refrigerating perishable food promptly if it is not intended to be used immediately). Companies may also develop protocols for notifying consumers of unanticipated disruptions, such as delays caused by labor shortages or extreme weather, and what to do if packages arrive late or if they have concerns regarding their deliveries.

B. Temperature Control During Transportation and Delivery

Maintaining food at proper temperatures is critical to limiting the growth of pathogenic bacteria or the formation of microbial toxins in food. Thus, proper temperature control throughout production and delivery to the consumer should be an integral part of any DTC delivery operation. A DTC delivery company should identify required time and temperature parameters, validate and implement controls to meet these parameters, and verify that these controls are working effectively.

A DTC delivery company should identify the temperature requirements throughout transport and delivery based on regulatory requirements as well as the company's evaluation of its products, including their unique characteristics and uses. For example, a company that sells and delivers a variety of food types may require that its perishable refrigerated products remain at or below 41°F (5°C) and that its RTE hot-held foods remain at 135°F (57°C) or above to be consistent with the standards specified in the FDA Model Food Code. The company would then conduct validation activities to identify measures that will adequately maintain required

temperatures and control the microbiological risks posed by the product during all stages of production, transport, and delivery.

Conducting temperature-control validation

Temperature requirements can be met using a combination of different controls at various stages of a company's operation. These controls can include limiting the maximum delivery time, using appropriate types and amounts of refrigerants or coolants, and requiring a specific initial product temperature. These controls can interact together to affect temperature, and it is critical that these controls be validated.

In conducting validation activities, a company should account for all possible variables that may compromise temperature control. With respect to transportation and delivery, for example, some businesses conduct same-day or overnight delivery and can control the longest possible delivery time (e.g., by restricting delivery ZIP code). Companies with less control over delivery times should account for this variability. Validation studies should also take into consideration the type of food, the organism(s) of concern, and the growth limit targeted. DTC delivery companies should also consider validating contingency measures for emergency situations that may compromise temperature control, such as power outages, refrigeration equipment breakdowns, or delivery-route disruptions. For further discussion of potential emergency considerations, see *Emergency Action Plan for Retail Food Establishment*, CFP 2014 (providing guidance for addressing emergency situations, including interruption of electrical service, floods and fire).

Examples of potential approaches for verifying temperature controls include testing temperature profiles and packaging configurations in a simulation chamber and conducting periodic shipment tests using data loggers and trained participants in various geographical areas. One recommended best practice is to simulate "worst-case scenarios" and show that product temperatures are lower than the targeted temperature at the end of the longest possible time to receipt by the final customer. A worst-case scenario should be based on the farthest, warmest locations to which food is shipped, accounting for historical temperature data and depending on where the food originates.

- *Example*: a company manufactures a variety of perishable, refrigerated products and delivers to consumers in all states and zip codes. The company determines that these products must not exceed 41°F at any time throughout transportation and delivery. In designing a study, the company identifies Phoenix, AZ; Dallas, TX; and Miami, FL; as the farthest, warmest locations from each of its respective distribution centers. The company then conducts a study to identify the packaging configurations and maximum delivery times that will maintain the required product temperature throughout delivery to each of these cities. This company conducts in-house testing and also elects to engage an external food safety laboratory to conduct several additional simulations to confirm its findings.

A company may determine that limited periods outside of required temperature parameters do not result in an increase in risk, but any such acceptable periods will depend upon the

combination of time and temperature and may require a variance from the regulatory authority. In establishing product temperature limits and any durations during which those limits may be exceeded, a DTC food delivery company should assess the microbiological risks posed by the product and ensure they are adequately controlled until delivery to the final consumer within the delivery period.

Validation studies should be supported by relevant scientific or technical literature, pathogen predictive growth models or actual pathogen growth experiments. Resources regarding temperature control and pathogen growth risk can be found in Appendix B.

C. Choosing Packaging

A DTC delivery company should determine appropriate packaging elements based on the specific details of its products and delivery models.

While a company should consider all packaging possibilities that are appropriate for its products, in this section, we focus on three primary packaging elements: outer (i.e. tertiary) packaging, refrigerants/coolants, and dunnage.

Outer packaging

Outer packaging can function as an insulator, keeping cold air in and warm air out. Any damage to the outer packaging could expose the contents to contamination or to loss of temperature control, so a company should ensure that the outer packaging maintains its integrity during transit and protects the contents from damage. A company may choose to conduct specific crush tests and may consider providing carriers with instructions for handling packages in transit.

Where a company determines that more sophisticated outer packaging is needed, solutions combining packaging and refrigerant systems are available. Before purchasing a solution, the company should ensure that their needs are covered by the validation of that solution, i.e. that the parameters (e.g. time, external temperature) used for the validation exceed those of the use case. Alternatively, the solution provider may have a computerized simulator to demonstrate the suitability of the solution for the company use case. In either case third-party validation is recommended.

Reusable packaging. Outer packaging can be disposable or re-usable. If re-usable, the collection logistics should be defined and communicated to consumers. Re-usable packaging should also be inspected, cleaned and/or sanitized before re-use to prevent contamination. Whatever contamination prevention process is chosen should be validated and verified to ensure effectiveness and suitability to the type of products carried.

Coolants

The need for a 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 during transit. Coolant selection should be based on validated scientific principles and data. For example, a company may consider seasonality or temperature fluctuations in choosing a coolant (see Section 5.B for further discussion of considerations in temperature validation).

Coolant options include, but are not limited to, simple ice contained in plastic, frozen gel packs, plastic packs containing a freezable solution, or dry ice. The efficacy of a coolant depends in part on the temperature at which it changes physical state as well as the mass and coolant type.

- Ice packs. Only potable (drinking) water should be used to make ice packs or provide the liquid in gel packs. Ice packs thaw at 0°C (32°F) and thus may not always be able to maintain appropriate temperatures compared to frozen gel packs. If ice packs are reused or recycled, they should be adequately cleaned and sanitized.

- Frozen gel packs. Depending on their composition, gel packs can thaw at temperatures below 0°C (32°F). When considering such products, a company should ensure suitability for use with food. Companies may consider testing gel packs for quality and/or integrity before use. As above, reused or recycled gel packs should be adequately cleaned and sanitized.

- Dry ice. Dry ice is commonly used as a coolant in packages containing frozen food and sublimates at -79°C (-109°F). It may produce colder temperatures than ice or gel packs; however, since dry ice is so cold, it may also affect the quality of certain sensitive foods (e.g., produce). The use of dry ice requires extreme care for several reasons, including safety and environmental concerns, so companies using dry ice should inform workers of potential risks and best practices for handling dry ice. Companies may also consider including warnings for consumers related to the safe handling of dry ice. Shipping dry ice may be subject to specific regulatory requirements.

Companies should verify coolant packs will maintain their integrity and avoid compromising food safety. For example, if ice packs melt and leak, this may cause food to be submerged in water, potentially leading to cross-contamination or cross-contact.

Coolant packs are generally not appropriate for cooling of product but instead can be used to maintain product temperature at the time of packaging. Initial cold food temperature should ensure required temperatures are maintained throughout the transportation and delivery process. The placement of coolants within the packaging is equally important to ensure all parts of the food are kept at appropriate temperatures throughout the entire delivery process (see the discussion of validating temperature controls in Section 5.B).

Dunnage

Dunnage refers to the extra packing materials used to fill the voids in the package and secure and protect its contents during transportation. Use of dunnage may be critical in packaging

foods for delivery because it replaces air in the package and may help with insulation. Food in a package containing a refrigerant and air will generally heat up faster than a similar package where dunnage (e.g., paper, bubble wrap) replaces much of the air. Dunnage should be placed so it does not insulate the food from the refrigerant and should be of adequate sanitary quality.

D. Preventing Contamination

Preventing cross-contamination is a key aspect of food safety whether these are biological, physical, or chemical contamination risks. Biological risks are discussed elsewhere in this document in detail. Physical risks include materials that can injure the consumer such as glass fragments, metal shards or rocks. Chemical contamination risks include toxins and allergens as well as intentional contaminants. Individual components of a delivery need to be packaged so cross-contamination does not occur during transport. The outer container of the delivery must be able to maintain integrity during transport. Sealing may be a useful means to prevent intentional adulteration. Items being delivered need to be transported in a clean and sanitary manner and transported so the food product does not become contaminated.

Any materials used for wrapping and packaging should not to be a source of contamination. These materials should be stored so they do not become contaminated. Any wrapping and packaging operations should be carried out in a manner where contamination of the food is prevented. Where pre-packaged foods are delivered 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 a package, appropriate measures should be taken to prevent leakage and cross-contamination to other foods or packaging materials.

Proper packing also serves to prevent chemical and physical contamination of foods. Food delivery companies should be aware of the chemical and physical risks posed by delivering non-food items together with food items. Food delivery companies should be aware allergens constitute a chemical hazard to be managed. Companies should 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 delivery. More details on allergens and their risks can be found in the FDA model Food Code, Appendix 3 Food Allergen Labelling and Appendix 4, Food Allergens as Food Safety Hazards.

E. Other Delivery Considerations

Choice of carrier. This will depend on a range of factors, including the size and weight of packages, availability of service, general reliability, historic performance, and commercial viability. Specialized delivery services utilizing refrigerated transport may be appropriate. Since some carriers may not deliver 7 days a week, some companies may choose to ship only certain days of the week to ensure timely delivery.

A DTC delivery company should be aware its 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 DTC delivery company should not expect their package

to receive any "special treatment" unless it is part of their agreement with the carrier. The DTC delivery company should verify any enhanced level of service promised by a carrier before relying upon it or modifying any established temperature-control requirements, including packaging and cooling.

Signature requirements. Some carriers offer the option of signature release (i.e., requiring a signature for delivery). This has the advantage of ensuring someone is immediately available to receive and refrigerate the food upon receipt. It presents the challenge of delaying delivery in the case a signatory is not available.

Non-delivery. 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.

F. Food Safety Training

Food safety is a responsibility shared by everyone involved in handling, processing, storing, packing, or distributing foods for DTC delivery. A DTC delivery company should ensure adequate food safety training and supervision for all personnel handling food. A DTC delivery company should ensure personnel handling food are adequately supervised and instructed to ensure they work in sanitary conditions and in accordance with proper food safety procedures. Continuous supervision is critical to ensure compliance. Such supervision is typically performed by an individual designated as the Person in Charge (PIC) in a retail environment. The PIC should always be appropriately trained according to applicable regulations or internal requirements so as to ensure good food safety practices. Where an operation employs only one or two people, supervision may not be applicable.

Training involves an overview of food safety principles as well as specific instructions, commensurate with the trainee's responsibilities, for promoting food safety in day-to-day operations. Companies should also ensure those responsible for developing and maintaining a company's written food safety program have the necessary qualifications and experience (e.g., food protection manager certification).

General principles

Training should be given by qualified and competent persons or provided using online or other resources. Companies should have a plan to (a) identify the training needed for everyone whose activities may impact food safety and (b) keep records which confirm this training was completed satisfactorily. These records can help a company demonstrate it has a satisfactory food safety management system, and evidence of training in personal hygiene and food safety management may be very important for substantiating compliance.

Training needs and effectiveness should be assessed regularly. Certain food safety training may need to be implemented annually and ongoing training may also be necessary. A training program should also be updated to reflect operational or business changes (e.g., new products

or packaging methodology which may raise new food safety issues and concerns). A company can develop its own program or incorporate existing established curricula. These curricula often have documented course instruction notes, which can help to ensure consistency.

A company may also determine personnel other than those who handle food may need to undergo training. For example, personnel such as custodians, sanitation crews, maintenance workers, and others with access to a company's operations may need training in certain food safety practices.

Conducting training

DTC food delivery companies should ensure personnel handling food and packaging for direct food contact receive training in the food safety practices appropriate to their duties. The training provided should ensure that such personnel have appropriate knowledge to handle food safely. This knowledge can be obtained in various ways, including on-the-job training, self-study with recognized guidance materials, formal training courses, and prior experience. Arrangements should be made for persons whose first language is not English and/or persons with learning or literacy difficulties.

A training program should be based on the food safety practices relevant to a company's operations, e.g., preventing cross-contamination, using appropriate packaging, implementing temperature-control requirements, and managing health and hygiene.

A DTC delivery company should contact the relevant regulatory authorities to determine any applicable training requirements. For example, see Section 2-103.11 Person in Charge and Annex 3, Section 2-103.11 of FDA model Food Code for a discussion of the training requirements for a person in charge. The FDA model Food Code also requires the person in charge must be a Certified Food Protection Manager (CFPM). A CFPM is an individual who has demonstrated by passing a food safety certification examination from an accredited certifying organization that he or she has the knowledge, skills and abilities required to protect the public from foodborne illness.

G. Consumer Communication

A DTC delivery company should identify the food safety information which should be included within a package and/or in other communication channels, including on a product website or via email. This may include product information as well as consumer instructions for communicating feedback and concerns.

If food safety labeling is included on the outside of a package, a DTC delivery company should ensure it is not obscured, including by any labels a third-party carrier may affix to the package.

Product information

Products for DTC delivery should be labeled according to applicable regulatory requirements. This includes following federal, state, and local regulations for nutrition information and

allergen disclosure. All partners should work together to ensure all relevant food safety information provided at the point of sale, including on product websites or mobile applications where orders may be placed, is accurately communicated.

Companies should advise consumers of when to expect their orders and what to do upon delivery. If directions are not already specified on the product label, the company should advise the recipient that such contents are perishable and should be refrigerated or frozen upon receipt if not used immediately. This is especially important if the package is sent as a gift, if the recipient may not be aware of the contents, or if the outer packing obscures the product label.

Companies may also need to provide consumers with updated information relevant to food safety after their orders have been placed. For example, a delivery may arrive late due to unexpected transportation delays. Depending on the extent of the delay and the nature of the food, a company may decide to inform the consumer that certain perishable items should be discarded. Sourcing challenges may also require changes to the allergen information required for a product, so companies should ensure they have processes in place to communicate updated allergen information to consumers when needed.

Product information may also include instructions for safe use, such as information about any raw product or raw ingredients that may pose a health risk and are intended to be consumed raw (e.g., raw milk cheeses or sushi-grade fish). Companies may also choose to provide consumers with guidance on safe food storage, handling, and preparation.

Instructions for consumer feedback and concerns

We recommend DTC delivery companies also provide consumers with information about what to do if they are concerned about the safety of the product, such as when a delivery appears to have been tampered with or if the packaging has otherwise been compromised. In most cases, consumers should be informed of how to contact the company directly to resolve concerns. Consumers also have the right to contact the appropriate regulatory agency if they have a concern. In such circumstances, companies can prepare to respond to any concerns by having standard operating procedures, process records, and other appropriate documentation in hand. These records will assist with reported alleged foodborne illness and potential regulatory investigations.

Some companies may choose to label certain items with the date and time packaged and/or the shipping date. If a product's package has been manipulated in any way, the label should be updated to reflect the repackaging date.

H. Best Practices for Managing a DTC Delivery Food Safety Program

Responsibilities for implementing food-safety control

To promote the implementation of food safety controls, a DTC company should assess its business model and supply chain, including partnerships and agreements with other parties. The parties involved at each stage of the production and distribution chain should collaborate

closely, and companies should also consider defining food safety responsibilities in formal agreements between parties. Clear procedures for communication between the DTC company and its partners will be helpful for sharing compliance information, food safety concerns, and relevant operational changes in a timely manner.

Examples of expectations that can be reflected in agreements include:

- Responsibility for conducting validation and/or verification
- Managing non-conformances, including communication and escalation requirements
- Conducting training
- Complying with applicable food safety laws/regulations
- Implementing various food safety measures (e.g., meeting time/temperature limits, preventing contamination)
- Implementing employee health policies
- Emergency protocols or contingency plans
- Personnel standards (e.g., selection criteria, health and hygiene requirements, background checks)

Monitoring

As discussed in Section 4.B, a DTC delivery company should validate the measures necessary to control any food safety risks arising in the company's operations. The company should then conduct verification activities to demonstrate whether the validated measures are being effectively implemented.

As a critical component of a food safety program, a comprehensive monitoring system helps verify food safety policies and systems are being applied in a consistent and sustainable manner and identify continuous improvements or corrective actions.

In designing its monitoring approach, a DTC delivery company should consider the following:

- Which validated food safety measures should be monitored
- Where monitoring will occur, whether in production, transportation, and/or upon delivery
- How monitoring will be conducted for each food safety measure
- How the monitoring system will be described and communicated (e.g., in written policies and procedures)
- How often each monitoring tactic will be implemented
- Who will be responsible for conducting monitoring
- How deviations will be addressed
- How monitoring results will be recorded (e.g., including the signature of the person completing the monitoring)
- What consumer inquiries and complaints have been received

Developing a Monitoring Approach

A monitoring system should be based on the validated measures a DTC delivery company has identified are needed to control its food safety risks. A company should evaluate each validated risk-control measure to determine the best approach for monitoring, considering the type of data to be gathered, how the data will be used, how frequently the control measure should be evaluated, who should gather and/or interpret data, which key performance indicators should be used, and how monitoring results should be reported.

There are multiple tools which DTC delivery companies can consider incorporating into a monitoring system. Examples include:

- *Process Self-assessments*. Regular internal assessments can help a company's personnel to proactively address food safety risks and prepare for external audits and regulatory inspections. These assessments can include daily checklists, shift-based logs, internal reviews, and third-party audits. The type and frequency of such assessments should be appropriate for the complexity of the company's operations and products.
- *Process Audits*. A process audit is a formal inspection usually conducted by a third party. A DTC company can partner with a food safety auditing firm to design and implement an audit to determine if food safety risks are being controlled throughout the supply chain and delivery.
- *Inspection upon delivery*. A DTC company can employ its own personnel or third parties to confirm whether delivery parameters are met. For example, a company may consider assigning an individual or group (e.g., company employees or third-party "mystery shoppers") to replicate the consumer experience and provide feedback on the delivered product. This person or group can examine parameters such as product labeling, temperature controls, transportation times, package integrity, and the effectiveness of packaging in preventing cross-contamination.

Using Internal and External Resources

A DTC delivery company should consider the complexity and risks associated with its operations when using internal and/or external resources for monitoring its food safety system. Depending on the scope of the business, both options may be useful, and a DTC company should weigh the benefits of employing these resources when making decisions based on their program needs. Regardless of whether they are employees or third parties, all personnel selected should have the expertise and proper training necessary to correctly and consistently carry out their assigned tasks.

Technical Tools

A variety of monitoring tools are available to help DTC delivery companies monitor compliance. Companies should identify the most current technologies available to aid with capturing and maintaining data. Companies may choose to use equipment, such as temperature monitoring devices for food products, hot and cold holding equipment, refrigerated compartments, insulated carriers, and other packages; geo-tracking devices, cameras, video recording devices, web platforms/portals, and other technological solutions.

Companies should ensure measurement methodology is precise and the correct tools are being used for both food products and equipment. For example, probe thermometers should be used to measure internal product temperatures, and appropriate equipment thermometers should be used to measure ambient temperatures of refrigeration and hot holding equipment. Waterproof thermometers are also available for dishwashing machines. Temperature indicators can also be used for packages during transport and delivery. For accuracy, thermometers should also be regularly calibrated, either daily or per the manufacturer's directions. For further resources, see Appendix A.

Companies should consider systematic approaches to assist with compiling data. Software programs can be custom designed to include a variety of hierarchies and data fields, such as menu items, delivery types, delivery times, product and equipment temperature readings, and regulatory checklists. Food safety experts and analysts can use the data to gain insights, evaluate root causes, determine if corrective action plans are effective, or make program adjustments as necessary.

Managing noncompliance and continuous improvement

Once a system is in place to monitor the key components of a food safety program, companies should establish processes to address noncompliance and improve risk management. These processes should include expectations for communicating non-conformances and performance metrics (e.g., temperatures at various critical control points). For example, including an escalation process to relay non-conformances to the appropriate individuals and departments can help ensure issues are addressed promptly. Companies should ensure qualified individuals have the authority to take corrective actions.

As part of its efforts towards continuous improvement, a DTC company should also continually research the most current food safety innovations and technologies in the manufacturing and retail food industry. Remaining up-to-date on industry trends can assist an organization in having awareness of the best available food safety tools can help it be more efficient, more quickly respond to alerts, take corrective actions, and adjust food safety procedures.

Traceability and recalls

In the case of a foodborne outbreak or recall, DTC companies should have processes that allow public health officials to request relevant traceback and trace forward information that would aid in their investigation. This information should be shared in accordance with relevant privacy laws. For more information of traceability and recalls see Appendix A.

Corrective and Preventive Action Plans

Incorporating corrective and preventive action plans into food safety monitoring is essential for controlling food safety risks and preventing repeat occurrences. Corrective and preventive action plans are applicable regardless of whether internal and/or external personnel are involved in monitoring. The action steps and urgency assigned should be appropriate to the level of risk.

When SOPs are developed, a DTC company should identify 1) corrective actions for the disposition of the affected items and 2) separate preventive actions, tailored to potential root causes, to ensure the problem does not recur. For example, a company may determine a perishable food must remain at 41°F or below but finds an instance in which the food exceeds this temperature for several hours due to equipment failure. The company may decide the corrective action is to discard the food, and the preventive action is to install monitoring and alert sensors for refrigerated delivery equipment. An alert is used to notify appropriate parties when the air temperature exceeds 41ºF for a designated period. The organization is then able to eliminate a food safety risk to the consumer and prevent product loss.

When developing corrective and preventive control plans, companies should consider the following:

- Engaging stakeholders (e.g., representatives from food manufacturer/food establishment, product delivery/transportation company, or external auditing firm)
- Establishing requirements for communicating non-conformances, including timing protocols based on potential risk
- Determining what parties must be notified and level of escalation based on risk
- Identifying who is responsible for implementing the plan
- Monitoring corrective and preventive actions to ensure they are effectively implemented
- Incorporating root cause analyses to assist with corrective actions and adjustment of protocols as needed
- Conducting targeted training for personnel to identify and correct errors in the food safety management program
- Using accountability models (e.g., number of higher risk occurrences triggering escalation)
- Reassessing studies or procedures to determine if improvements are needed to resolve operational or behavior-related occurrences (may be part of recurring re-validation activities)

6. *Third-Party Delivery guidance*

A. Food Safety Responsibilities

All parties engaging in Third-Party Delivery Service should understand the relevant food safety risks and define roles for such parties to help minimize those risks. The parties to the business agreement should clearly identify the responsible party during each stage of the flow of food, from preparation, staging, and delivery.

B. Preventing Contamination

Food contamination refers to the presence of biological, chemical, and/or physical contaminants in food which can cause foodborne illness or injury. Biological contamination can occur through improper food storage and lack of temperature control during preparation, packaging, and delivering of food. Chemical contamination can occur when non-food products, such as household cleaners, personal hygiene items, etc., are packaged with food products in the same delivery bag during packaging. Physical contamination can occur if food products are not packaged appropriately or protected from the external environment.

Preventing contamination is a key aspect of food safety. Food establishments and food shoppers should minimize contamination risks by determining which items will be segregated and how items should be packaged. An added challenge in third-party delivery from food establishments is that various food and non-perishable food products may be delivered together. Best practice is to (a) separate ready-to-eat foods from raw proteins; (b) separate chemicals and non-food products from food products; and (c) separate glass and other fragile food products to reduce breakage risks. Separation options may include separate bags or the use of another barrier.

The food establishment should have processes to determine whether food deliverers may prepare beverages, collect accompanying utensils, napkins, straws, or condiments, or package foods.

Time/Temperature Control

Temperature control should be considered when delivering food to the consumer through the use of a food deliverer. However, time as a public health control is also acceptable for limiting pathogenic bacterial growth. A wide variety of transportation vehicles are used to provide delivery services. A refrigerated or freezer vehicle may be ideal in maintaining temperature control. If the transport vehicle does not have a mechanism to control the ambient temperature of the vehicle, food deliverers should address all relevant food safety concerns and hazards when transporting the food. Food deliverer procedures may include the use of insulated delivery bags, containers, or coolers, or use of coolants to keep foods hot or cold.

Food ordering platforms should issue guidelines to food deliverers to deliver orders safely and in accordance with relevant safety standards, and to follow any food establishment delivery guidelines that are meant to promote food safety and compliance with applicable regulations.

The food ordering platform, food deliverer, and food establishments should work together to develop appropriate procedures to prevent pathogen growth during handling, transport, and delivery. Whereas time may be an appropriate control measure during short delivery periods, additional control measures should be considered for longer delivery periods or when food is not handed directly to the consumer to ensure perishable items remain at proper temperatures.

Temperature Monitoring for Staging Foods at Food Establishments
Foods held in a staging area should be maintained by food establishments at proper product temperatures prior to pick-up and delivery by a food deliverer. A temperature monitoring process for staging foods at food establishments may be needed to ensure food is maintained at the proper temperature until ready for pick-up and delivery to the consumer.

Packaging
Packaging protects and separates products from contamination, the external environment, and physical damage. Packaging design and using multiple layers of packaging, including primary, secondary, and tertiary, minimizes the risks associated with contaminants and food safety hazards. Primary and secondary packaging, such as foil wraps, direct food contact containers, and plastic bags, directly protect the food. Tertiary packaging or outer packaging, such as delivery bags or coolers, provide protection from the external environment including extreme temperatures, direct sunlight, weather (e.g. rain, snow), road debris, and animals and pests.

The primary and secondary packaging should not be re-used by food establishments. The tertiary or outer packaging should be constructed of durable and easily cleanable materials for re-use to transport food during deliveries.

Food establishments and food deliverers should determine correct storage (e.g. upright) and amount of food to be packaged during transportation to avoid crushing of food or damage to primary food containers that could potentially contaminate other food or lead to unclean delivery bags.

Food Tampering
Prevention of food tampering activities occurs through packaging design and tamper-evident devices. Food establishments may utilize primary packaging that cannot be resealed, such as tear strips, and secondary packaging, such as bags or boxes, with tamper-evident tape, stickers, or seals to deter food tampering activities during food delivery and maintain food safety and integrity.

Food deliverers should not remove food products from the secondary or tertiary packaging until delivered to the consumer. Food deliverers and food shoppers should not open, alter, tamper with, or change the primary or secondary packaging.

Delivery Bag Usage, Maintenance, and Cleanliness
Food deliverers may use insulated delivery bags that help minimize food temperature fluctuations and/or help maintain food temperatures during delivery to the consumer. In addition to insulated delivery bags, food deliverers can add other refrigerants or coolants, such

as ice and/or gel packs, which may help reduce the rise in product temperatures during extended delivery times.

Delivery durations, ambient temperatures and conditions, and intended food temperatures at delivery may assist food deliverers with identifying the need to use insulated delivery bags. Delivery bags can be designed and manufactured to support a variety of business needs. The materials, construction, and design of the delivery bag can be customized to maintain food hot or cold and can be designed with pouches to separate cold food from hot food.

Food ordering platforms or food establishments may set guidelines for food deliverer delivery bags, especially for extended delivery times, which may help maintain the food at safe temperatures during delivery to the consumer. Guidelines may include the appropriate choice of delivery bag or other packaging, as well as who will provide the bag or packaging, how to obtain new or replacement materials (e.g. methods, costs, etc.), and whether these materials are mandatory or whether food deliverers can choose to use alternative options.

Delivery bag durability and lifespan will vary depending on construction, materials, usage, and maintenance; however, delivery bags should be easily cleanable, kept clean, and maintained in good repair. Delivery bags should be cleaned daily, or more frequently if needed. Food deliverers should check the delivery bag condition for rips, tears, holes, and food debris that could lead to contamination and entry points for pests, etc. Recommended best practice is to check delivery bag condition after each consumer drop-off and prior to the next food delivery and to remove food debris and clean up spills or leaks. The food deliverer should be responsible in ensuring delivery bag condition and maintenance.

Some third-party delivery service entities offer personal shopping services in addition to delivery services. Food shoppers might also utilize bags during selection and packing of products and should ensure bags are clean and in good repair.

Vehicle Cleanliness and Inspections
A variety of vehicles or transportation methods (e.g. walkers, cars, motorcycles, bicycles, autonomous vehicles, or drones) may be used to transport food depending upon the delivery location and accessibility. Vehicles should be clean and free from odors, pests, animals, and any other materials that could adversely impact food safety. Food deliverers should inspect vehicles frequently to ensure that vehicle interiors are clean and free from debris. Food ordering platforms should provide food deliverers with information on maintaining their vehicles in safe conditions, such as vehicle cleanliness and maintenance.

C. Food Safety Education and Training

Food ordering platforms should make available or provide relevant food safety education or training to food deliverers and food shoppers. Food safety education or training may be offered internally or externally through an outside education or training program.

Food deliverers and food shoppers should have appropriate knowledge of basic food safety principles through the completion of a food safety education or training program. Food safety education and training programs for food deliverers and food shoppers may cover topics

including: (a) contamination prevention; (b) product segregation; (c) temperature management; (d) health, hygiene, and hand washing; (e) product tampering prevention; (f) allergens; (g) vehicle transportation cleanliness; and (h) proper selection and use of clean, insulated delivery bags.

Food shopper's education or training may also cover additional topics including: (a) proper order of product selection, such as picking shelf-stable items first, frozen items second, cold refrigerated items third, and hot, prepared items last; (b) proper selection of products with the farthest use-by-date code and intact packaging; and (c) final product handling and packaging.

Additional knowledge areas may include, but should not be limited to: (a) when to pick/pull perishable and non-perishable food products; (b) preparation time needed for food products to be assembled; (c) staging food products utilizing dry storage shelves, refrigerators/coolers, and/or freezers; (d) instructions on foods for delivery (e.g. perishable vs non-perishable); and (e) modes of transportation to be used for delivery (e.g. personal vehicle, bicycle, motorcycle, commercial vehicle, etc.).

Education and Training Topics

Prevention of contamination, temperature control, and personal health and hygiene should be areas of focus for food safety education and training to prevent foodborne illness and minimize food safety risks.

Contamination

Food deliverers and food shoppers should be aware of any sources of potential contamination. Food contamination could occur from various sources, including but not limited to: (a) food deliverer or food shopper themselves; (b) bags, coolers, or other methods used to transport the food; (c) external environment; (d) animals and pests; and (e) mode of transportation.

Temperature Control

Food deliverers and food shoppers should know the correct hot and cold holding temperatures for food and understand the food safety implications of holding time temperature controlled food for safety (e.g. TCS foods) in the temperature danger zone for an extended period of time. Food deliverers and food shoppers should also have knowledge of the necessary equipment, such as insulated bags, coolers, and/or coolants that may be needed to safely hold food at proper product temperatures or help with temperature control. Familiarity with temperature measuring devices is also recommended when relevant.

Personal Health

Food deliverers and food shoppers should not work while ill. Viruses, bacteria, and parasites can all be potentially transmitted from an ill individual to food and/or the recipient of the food via direct contact and packaging. Food deliverers and food shoppers should not work with food if any of the following symptoms are present, including: (a) vomiting; (b) diarrhea; (c) jaundice (yellowing of the eyes and skin); (d) sore throat and fever; (e) infected skin lesion; or (f) have been diagnosed with Norovirus, Hepatitis A, *Shigella* spp., Shiga Toxin-Producing *Escherichia coli*, Typhoid fever (caused by *Salmonella* Typhi), or *Salmonella* (nontyphoidal). Food

deliverers and food shoppers who have been exposed to a foodborne pathogen from a household member with symptoms or diagnosis above should also not handle food.

Personal Hygiene
Food deliverers and food shoppers should understand the importance of good personal hygiene, including wearing clean attire. Food deliverers and food shoppers should: (a) practice good personal hygiene; (b) know when hand washing is needed and how to effectively wash hands; (c) know how to avoid bare hand contact with ready-to-eat foods; and (d) know how to use provided utensils to handle food when necessary.

Food ordering platforms should have standards to address food deliverers and food shopper's behaviors that may pose food safety risks, such as eating, drinking, chewing gum, or utilizing tobacco and similar products during food selection and deliveries.

D. Management of Non-Compliance

Food ordering platforms should have processes developed to address consumer feedback and issues of non-compliance as further described herein. Agreements between the parties and food ordering platforms can be used to outline the expectations of each party. Issues of non-compliance may include potential food safety concerns (e.g. reported incorrect food temperatures, allergens, foodborne illness, product adulteration, etc.), food quality concerns (e.g. broken, damaged, spoiled, etc.), wrong products (e.g. reported allergens), and delivery concerns (e.g. reports that deliveries were not delivered within specified timeframe). While product quality is outside the scope of this document, some consumers may perceive product quality issues as relating to food safety.

Food ordering platforms should determine (a) how issues of non-compliance and consumer feedback will be handled; (b) what guidance is provided to the consumer regarding any food products in question; (c) who receives the notification and/or feedback; and (d) who reviews reports and provides resolution.

Food ordering platforms may issue guidance to food deliverers for handling various logistical situations, including appropriate next steps, such as whether the food product can still be delivered, returned, or discarded. Some examples of situations that should be considered include (a) the food deliverer arrives to drop off the food order at the correct delivery time and location, but the consumer is not present for the delivery drop-off; (b) food products show evidence of tampering or alteration by someone other than the deliverer (e.g. loss of package integrity or seal); or (c) food products are damaged, spilled/leaked, or otherwise contaminated (e.g. hair, dirt, debris).

Processes should also include a mechanism for the consumer to contact the food ordering platform and provide feedback on the food order(s) or delivery service. The food ordering platform should monitor consumer reports and non-compliance issues as needed to determine whether their process is effective or if they should consider revisiting their process.

E. Other Food Safety Considerations

Food Allergens

Food establishments typically do not make claims or guarantees that their kitchen or prep areas are allergen-free environments or that cross-contact with allergens will not occur as food establishments may prepare products that contain allergens on similar surfaces and equipment. The food establishment may consider providing allergen awareness information through the food ordering platform. Food ordering platforms may include features to suggest substitutions when an ordered product is no longer available. When such features exist, consumers should be reminded about the allergen potential risk created by substitution options.

Traceability and recalls

In the case of a foodborne outbreak or recall, food ordering platforms should have processes that allow public health officials to request relevant traceback and trace forward information that would aid in their investigation. This information should be shared in accordance with relevant privacy laws. For more information on traceability and recalls see Appendix A.

Technology and Innovation

Incorporating and leveraging technology may be advantageous to provide notifications to consumers if deliveries have encountered unexpected or excessive delivery delays.

7. Appendices

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 which handle food are licensed in some manner. DTC food delivery companies should contact the agency which issues their license or permit if they have questions about the food safety regulations which apply to their operation. If a DTC food delivery company is unsure who issues their license or permit or if one is required at all, the company should contact their state or local health department. The health department can assist or direct the company to the appropriate agency. DTC food delivery companies can also follow this link for state health department information: https://www.foodsafety.gov/about/state/index.html.

Food establishments and food ordering platforms may contact state, local, tribal, territorial or federal food regulatory agencies if questions or issues arise about food safety regulations which apply to their operation.

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 DTC delivery 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:

> (4) 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; (FDCA 21 USC §342(a)(4), FMIA 21 USC §601(m)(4), PPIA 21 USC §453 (g)(4))

The FMIA specifically prohibits adulteration during transportation:

> … any act while they are 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, DTC delivery foods must always be transported in a way which minimizes the risk of contamination and potential adulteration of the food.

Food regulations

Federal regulations also address sanitary situations which apply to transportation of foods. Some (but not all) of these regulations are provided below for reference.

The FDA Good Manufacturing Practice Regulations address warehousing and distribution as follows:

> §117.93 Warehousing and distribution.
>
> Storage and transportation of food must be under conditions which will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

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.

There is also the FDA Sanitary Transportation of Human and Animal Foods rule. See the following links for more information:

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm
https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM553930.pdf

The Sanitary Transportation of Human and Animal Food is designed to prevent transportation practices which 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 food. The FSMA requirements do not apply to transportation by mail, air, or third-party delivery service 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.

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. DTC food delivery 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

FDA's 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 which 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 and provides rules which may be relevant to packing and shipping of DTC delivery foods. The FDA Food Code can be obtained here: https:// www.fda.gov/foodcode.

USDA provides the following consumer information 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 your 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 which have been validated to deliver appropriate temperature control. Make sure perishable items and the outer package are labelled 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. Your company 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). Your company 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 DTC food delivery companies need to ensure the labeling of food is correct and not misleading and the food's chemical composition and any materials and articles which come into contact with the food are not harmful to health.

Where a DTC food delivery 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 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 but should take care to ensure the requirements have been satisfied.

If a DTC food delivery 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.

Some companies may choose to label certain items with the date and time packaged and/or the shipping date. If a product's package has been manipulated in any way, the label should be updated to reflect the repackaging date.

Traceability and recalls for direct to consumer and third-party delivery services parties

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 DTC food delivery companies and third-party delivery services (e.g. food ordering platforms and retail food establishments). Any DTC food delivery company and third-party delivery services should have four key aspects of their food safety system in place which relate to recalls:

- Means for tracking all recalls 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.
- Means to stop online sales once they learn of a relevant recall.
- Method to notify any consumers who have purchased a recalled product and inform them the product they purchased has been recalled.
- System to manage recalled inventory, to ensure any recalled product is appropriately tracked, controlled, and ultimately destroyed or reconditioned, and does not re-enter commerce.

DTC food delivery companies and third-party delivery services (e.g. food ordering platforms and retail food establishments) should be able to (a) provide trace-forward information to track where recalled product delivered to (e.g. consumer information) and (b) provide traceback information to track where recalled product originated from (e.g. distributor, supplier, manufacturer, farm).

Best practices for DTC food delivery companies and third-party delivery services (e.g. food ordering platforms and retail food establishments) are to have processes related to trace-forward and traceback actions developed and to have appropriate records to manage potential recalls.

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

B. Other resources

Relevant resources regarding temperature control

- 2017 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/UCM595140.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
- Centers for Disease Control and Prevention: Tips for Meal Kit and Food Delivery Safety https://www.cdc.gov/foodsafety/communication/food-safety-meal-kits.html
- Some states may have specific requirements for DTC or TPD food temperature control. Contact the state department that has jurisdiction over food regulations for details. Contact information for state departments of health and agriculture can be found at https://www.foodsafety.gov/about

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 http://browser.combase.cc/ComBase_Predictor.aspx?model=1

Procedures for taking food temperatures

The Food Code Annex 5, entitled "Conducting Risk-Based Inspections includes relevant information on temperature measurement in sections related to assessing temperatures (pages 608-612).

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 Hand Held Thermometer	Advantages	Disadvantages
Bi-Metal	Small – fits in pocket Inexpensive Can be calibrated	Requires frequent calibration 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 Fast response time	Most require manufacturer calibration Require batteries
Thermocouple	Very wide temp range (-60 to +2000°F) Fast response time Very accurate Ideal for all food temp's	Must be factory calibrated Expensive
Infrared	Fast response time Wide temp range (-25 to +900°F) Food contact not required Non-destructive	Measures surface temperatures only Used only as temperature indicator Not suitable for regulatory purposes

Employees preparing food within the DTC food delivery company prior to shipment should be trained on correct application, how to properly use and how to maintain the instruments 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 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/Transport

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

The FDA Model 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 variations.

C. 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 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 as long as the facilities which manufacture, process, package, or hold the products are registered with FDA, and prior notice of incoming shipments is provided to FDA. It should be noted that some facilities are exempt from registration. 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 not 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 also subject to prior notice requirements (for more information see 21 CFR 1.279(c)). For an article of food sent by international mail, prior notice must be submitted and confirmed by FDA before the food is sent. 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/media/118190/download

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/food-safety-modernization-act-fsma/background-fda-food-safety-modernization-act-fsma

The USDA Food Safety and Inspection Service (FSIS) is responsible for ensuring domestic and imported meat, poultry, and egg products are safe, wholesome, and accurately labeled. In addition, the primary inspection responsibility for Siluriformes fish, commonly known as catfish, was transferred to FSIS on March 1, 2016, for domestic producers and on April 15, 2016, for importers.

Foreign countries which export meat, poultry, catfish, and egg products to the United States are required to establish and maintain inspection systems which are equivalent to those of the United States. The USDA FSIS provides detailed guidance on steps to ensure that these 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

Here is a link to the USDA FSIS website regarding Siluriformes information: https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/siluriformes