



Description (Above): Food service operations in a shared kitchen.

4. Definitions

The following definitions shall apply for the purposes of these guidelines.

4.1 **“Incubator Kitchen, or Commercial/Shared Kitchen”** a fully equipped commercial food processing facility designed to allow multiple entrepreneurs or food processing operators to grow their businesses by providing a kitchen space with food and packaging equipment. For example, some new entrepreneurs might not be able to afford to build or buy their own kitchens, so they rent or reserve a shared kitchen on an hourly basis. This allows them to complete small-scale food processing in a shared kitchen used by multiple operators. They may be commercial kitchens, food hubs, or kitchens permitted by a regulatory agency, social club, church, firehouse, or other.

4.2 **“Incubator Kitchen Owner”** the owner of the commercial kitchen location to be rented.

- 4.3 **“Incubator Kitchen Operator”** a licensed person or company that rents space at the commercial kitchen location.
- 4.4 **“TCS Foods”** foods that require time and temperature control for safety and must be kept out of the Danger Zone (41-135* F) to limit pathogenic growth of microorganisms and the production of toxins. TCS foods include milk, eggs, fish, meats, untreated garlic and oil mixtures, raw seed sprouts, cut melons, cut leafy greens, and cut tomatoes.
- 4.5 **“Food Safety Operations”** the procedures and practices needed to comply with food safety regulatory requirements, including those pertaining to employee hygiene and practices, handwashing, use of gloves, safe food sources, safe food temperatures, cross contamination, and equipment cleaning and sanitizing.
- 4.6 **“Food Safety Standard Operating Procedures (SOPs)”** written practices and procedures that are critical to producing safe food. It is essential to have SOPs in place and to train employees and operators to use them.
- 4.7 **“Process Review”** a process whereby the manufactured product and written process is reviewed by a process authority, and food classification (such as low-acid, formulated-acid, high-acid, shelf stable, etc.) is determined.
- 4.8 **“Scheduled Process”** a process developed by a process authority and selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a product that will not permit the growth of microorganisms having public health significance.

5. Owner Responsibilities

- 5.1 Complying with all applicable state and local codes and ordinances. They should collaborate with regulatory agencies to ensure the

kitchen and all operators are properly licensed and/or permitted with the appropriate agency.

- 5.2 Maintaining the building and property in an acceptable sanitary manner, including pest control measures and sufficient garbage disposal.
- 5.3 Providing sufficient handwashing facilities, equipment washing and sanitizing facilities, and restroom facilities.
- 5.4 Maintaining an incubator kitchen operator schedule/calendar, including the date and time of processing. The calendar should be shared with the appropriate food safety regulatory jurisdiction when requested.
- 5.5 Limiting operations to only those for which the kitchen has the appropriate equipment, space, and facilities for production.
- 5.6 Maintaining a file for each kitchen operator, including but not limited to the business contract, business certificate, license, inspection results, and scheduled processes.
- 5.7 Identifying their rental capacity to regulatory representatives and not rent beyond the identified capacity. Incubator owners may not overbook, or schedule rentals in a manner such that the needed capacity exceeds the identified capacity and causes operators to process with insufficient production space.
- 5.8 Having a method for dealing with storage for clients' raw ingredients and finished product. This can be accomplished in various ways:
 - 5.8.1 Best practice indicates that individual operators' storage spaces should be separated in locked cages, if possible. All ingredients and finished products should identify the operator with designated storage spaces, labels, and tags, etc.
 - 5.8.2 Operators can rent their own off-site storage, which should also be licensed and inspected. If the operator does not need

storage, all ingredients must be purchased on the way to the kitchen and used during the rental period. Remaining ingredients must be discarded or used for personal consumption at home.

5.8.3 Finished products must be delivered to accounts directly after they are manufactured. They must not be stored. The kitchen manager is responsible for ensuring that all ingredients used are commercially sealed.

5.9 Providing guidance to incubator kitchen operators regarding:

5.9.1 Contract Agreements – The incubator kitchen owner/manager should discuss the particular contractual agreement between the incubator kitchen and incubator kitchen operator. The contract agreements may include, but not be limited to, rent, liability insurance, times of operations, list of foods to be produced in the kitchen, food safety SOPs, cleaning and sanitizing, regulatory agency inspection, and licenses and permits, etc.

5.9.2 Jurisdiction – Various food safety regulatory jurisdictions throughout the United States will be responsible for regulating incubator kitchens. The local health departments will have jurisdiction in other cases, while the state health or agriculture departments will have jurisdiction in others. Some states operate under a Memorandum of Understanding (MOU) which will determine the appropriate jurisdiction.

5.9.2.1 Once the appropriate jurisdiction has been determined, the applicant for an incubator kitchen license will undergo a consultation with a representative from the appropriate regulatory agency. An on-site inspection must be performed by the regulatory agency prior to issuance of the license. The consultation should include a review of proposed business practices, the type of equipment to be used within the facility, food safety operations, and proposed menus, to include a list of all food items that

the user intends to prepare, store, taste test, develop, package, or otherwise handle or use for food-related purposes.

5.9.3 As part of this consultation, the individual or entity should be required to provide a Food Safety Manager Certificate or equivalent in the licensee's name or in the name of an employee of the licensee, if the licensee intends to prepare, taste, handle, package, prepare for storage, serve, or otherwise use food, the name and address of the shared kitchen(s) the user intends to lease space from, the license number of the shared kitchen(s) the user intends to lease space from, and a signed statement of intent, or lease, from the owner or operator of each licensed shared kitchen that the applicant intends to lease space from, including the start date and end date (if applicable) for the agreement.

5.9.4 Based on the information provided, the regulatory agency will assess and assign a risk level to the shared kitchen user. That risk level will be based on criteria provided in these guidelines. Additionally, the regulatory agency will review its records on the licensed incubator kitchen to confirm it is properly licensed and capable of supporting the proposed practices. The menu or product list will be reviewed and approved.

6. Operator Responsibilities

6.1 Obtaining the appropriate regulatory agency license/permit.

6.2 Not commencing food processing prior to being inspected and/or prior to the submission of the appropriate license application.

6.3 Ensuring that all equipment is properly cleaned and sanitized prior to and subsequent to processing.

6.4 Addressing cross-contamination concerns for allergens and bacterial contamination, prior to and subsequent to processing.

6.5 Proper temperature controls of ingredients and finished product, including transportation.

6.6 Ensuring that all processing occurs at the incubator kitchen facility from start to finish. Product may not be moved to an unlicensed or uninspected facility for further processing. Products manufactured in unlicensed/unapproved facilities are subject to seizure and destruction. All ingredients must be from a known, approved source.

6.7 Verifying that all finished products and stored ingredients are appropriately packaged and labeled.

6.8 Ensuring that specialized processing operations, such as vacuum packaging, are not conducted if required approvals or documentation is not on file with the appropriate regulatory agency.

6.9 Evidence of Licensure – If an incubator kitchen operator has one or more employees, such employee(s) may work at the kitchen without the licensed user on the premises if all of the following requirements are met.

6.9.1 At least one employee possesses a Food Safety Handler Certificate or equivalent and is present when TCS foods are being prepared, tasted, handled, packaged, prepared for storage, served, or otherwise used, and

6.9.2 The incubator kitchen licensee keeps a copy of the following in the shared kitchen user's file:

6.9.2.1 A copy of the incubator kitchen user's employee Food Safety Handler Certificate,

6.9.2.2 The name and contact information (including home address and telephone number) of all employees (paid or unpaid), along with the date and times that all employees worked, and,

6.9.2.3 Records for a period of at least 60 days after the date of entry.

7. Regulatory Inspector Responsibilities

- 7.1 Scheduling the initial consultation and/or initial inspection.
- 7.2 The inspector should review with the incubator kitchen owner/incubator kitchen operator that food processing licenses and permits are location-specific and that all production, packaging, labeling, and storage should take place at the incubator kitchen. If applicable, the inspector should inspect off-site storage locations.
- 7.3 Confirm the operator's business information.
- 7.4 Confirm the operator's list of food to be processed at the incubator kitchen.
- 7.5 Conduct Risk Assessment: Determine if the product is shelf-stable, acidified, water-activity-controlled, vacuum packaged, etc.
- 7.6 Review and confirm if the operator requires a Process Review/Schedule Process for the intended food process. Verify the processes were prepared by an approved processing authority to assure the safety and integrity of the process and finished product. Regulator should obtain copies of the Process Authority letter and/or scheduled process.
- 7.7 Determine the applicable regulation under which the food produced will be regulated. Applicable regulations include:
 - 7.7.1 Local and state food safety regulations.
 - 7.7.2 FDA Food Code.
 - 7.7.3 GMP Regulations 21 CFR pt. 110 (old) cGMP Subpart B 117 (new).
- 7.8 Determine the applicable process-specific regulations, which include:

- 7.8.1 Fish and Fishery Products 21 CFR pt. 123.
- 7.8.2 Juice Products 21 CFR pt. 120.
- 7.8.3 Acidified foods 21 CFR Part 114.
- 7.8.4 Low-Acid Canned Foods 21 CFR pt. 113 LACF.
- 7.8.5 Alcoholic Beverages, including farm breweries, farm wineries, farm distilleries and farm cideries - applicable liquor authority license and GMP Regulations 21 CFR pt. 110 (old) cGMP Sub part B 117 (new).
- 7.8.6 USDA 9 CFR - USDA (United States Department of Agriculture), under the right conditions, would inspect a commercial kitchen if separation between official and unofficial establishments can be maintained.
- 7.9 Inspect the ingredients, food processing, food equipment, food assembly, and sanitary conditions of the premises.
- 7.10 Review production records, including cooking temperature records, pH records, thermometer calibration records, pH meter calibration records, product coding, and others.
- 7.11 Review recall traceability method.
- 7.12 Inspect packaging and labeling. The inspector should review all labeling requirements.
 - 7.12.1 The common and/or usual name of the product.
 - 7.12.2 The business name, business phone number, and business website (if any), of the shared kitchen user, along with the city, state, and zip code of the shared kitchen where the product was prepared or packaged.
 - 7.12.3 The net weight of the package.

7.12.4 A list of ingredients in the order of their predominance by weight with ingredients shown by their common or usual name, including all allergens.

7.12.5 A list of any artificial color, artificial flavor or preservative used.

8. Food Safety Controls for Consideration

8.1 Kitchen required to be licensed (nonfood processing), accountability.

8.2 Kitchen Owner – maintain operator schedule – maintain operator production records.

8.3 Kitchen required to provide storage (ingredients, finished product, packaging).

8.4 Regulatory agency / incubator kitchen owner should maintain open dialogue (new, inactive or OOB operators).

8.5 Food Safety Training requirement.

8.6 Compliance letters – inspection required.

8.7 License renewal – current inspection required.

8.8 Jurisdictions should maintain relationship and opened dialogue with each other.

8.9 Cross-contamination risk (multiple products).

8.10 Operating times (after normal working hours) – inspector scheduling.

8.11 Inspect during processing operations.

- 8.12 Obtain food processing license and do not return – manufacture at an unknown location.
- 8.13 Alter food processing (add high-risk processing and food items).
- 8.14 Process deviations and documented corrective actions.
- 8.15 Scheduled inspections.
- 8.16 Confirmed ingredient and finished product storage.
- 8.17 Tamper-proof ingredient storage (multiple users / competitors).
- 8.18 Issue incubator-kitchen-specific labels to assure food production at an approved source.

9. Evolution of a Shared Kitchen



Description (Above): Workers convene in a shared kitchen in the early 1900's.



Description (Above): Shared kitchen in the 2000's. Stainless steel, futuristic equipment.



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