



**Utah Department of
Agriculture and Food**

**Division of Regulatory
Services**

**4315 South 2700 West
TSOB South Bldg., Floor 2
Taylorsville, UT 84129-2128
Phone: (801) 982-2252
Fax: (385) 465-6023
udaf-estabregistration@utah.gov**

Manufactured Food Establishment Plan Review Application

The applicant must submit a plan review application at least 30 calendar days prior to operation.

*Note: The Utah Department of Agriculture and Food, Manufactured Food Regulatory Program, regulates products that are prepared and/or wholesaled to separate entities. Retail operations must complete a plan review application as directed by the Retail Food Regulatory Program (*UDAF Form PR101*).

Establishment Name: _____

Corporate Name (Parent Company): _____

Establishment Address: _____

City: _____ Zip Code: _____

Billing Address: _____

City: _____ Zip Code: _____

Owner Name: _____

Owner Phone: _____

Owner Email: _____

Contact Person: _____

Contact Person's Title: _____

Contact Phone: _____

Contact Email: _____

Architect/Designer: _____

Phone: _____

Date Plans Submitted ____ / ____ / ____	Projected Completion Date ____ / ____ / ____
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Check One: New Facility Remodel/Conversion of an Existing Facility

Customer Number of Existing Facility: _____

The following information is required to be submitted prior to review. Plans will not be accepted or reviewed until all items are submitted:

- Product list/categories
- Anticipated volume of food
- Proposed layout
- Mechanical schematics
- Construction materials
- Equipment layout and schedules
- Finish Schedule

<p>Fee Schedule: Plan review fees are nonrefundable and are based on the food establishment square footage (inspectable). Plans will not be accepted without payment.</p>	<p>Small: \$150.00 Medium: \$300.00 Large: \$500.00 Super: \$750.00</p>
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Check One:

- Less than 1,000 Square Feet (Small Establishment)
- 1,000 – 5,000 Square Feet (Medium Establishment)
- 5,000 – 50,000 Square Feet (Large Establishment)
- Greater than 50,000 Square Feet (Super Establishment)

For payment please contact the Utah Department of Agriculture and Food, Division of Regulatory Services at 801-982-2252 or by mail (written order check) to 4315 South 2700 West, TSOB South Bldg., Floor 2, Taylorsville, UT 84129-2128.

*Note: Prior to commencing food operations, the owner/operator must apply for a food establishment registration and successfully pass a pre-operational inspection. A notice of at least seven calendar days is required for all construction and pre-opening inspections.

Is your firm registered with the Food and Drug Administration (FDA) in accordance with the 2002 Bioterrorism Act?

Yes No

Will your facility meet Current Good Manufacturing Practice requirements at the time of the pre-operational inspection?

Yes No

*The following section must be completed by firms that manufacture, process, package, and/or hold **FOOD** as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (including raw materials and ingredients); firms not engaging in these activities may leave this section blank.*

(1) Indicate your firm's average annual sales (including subsidiaries and affiliates) of human food:

Greater than \$1,000,000.00 in annual gross sales (adjusted for inflation) over the previous three-year period.

Less than \$1,000,000.00 in annual gross sales (adjusted for inflation) over the previous three-year period.

(2) If your firm's average annual sales (including subsidiaries and affiliates) of human food are less than \$1,000,000.00, has your firm filed an attestation with the FDA to become a *Qualified Facility*?

Yes No Not Applicable

If your firm is a *Qualified Facility* and intending to engage in holding/storage activities of unexposed packaged food (requiring time/temperature control to minimize or prevent growth and/or toxin production of pathogens) have you established and implemented the modified requirements of 21 CFR 117.206?

Yes No Not Applicable

For information in regards to FDA attestation please see the following link:

<https://www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation>

**Note: Full implementation of 21 CFR Part 117, Subparts C (Hazard Analysis and Risk-Based Preventive Controls) and G (Supply-Chain Program) does not apply to a qualified facility. Qualified facilities may be subject to modified requirements of 21 CFR Part 117, Subpart D.*

(3) If your firm's average annual sales (including subsidiaries and affiliates) of human food are *greater* than \$1,000,000.00, have you fully written and implemented a food safety plan as required by the FDA Food Safety Modernization Act (FSMA), Preventive Controls for Human Food (PCHF)?

Yes No Not Applicable

Indicate which of the following food safety plan requirements you have prepared and implemented: (Check all that apply)

- The written hazard analysis as required by 21 CFR 117.130(a)(2).
- The written and implemented preventive controls as required by 21 CFR Part 117, Subpart C.
- The written supply-chain program as required by 21 CFR Subpart G.
- Established and maintained records as required by 21 CFR 117 Subpart F.

**Note: 21 CFR Part 117, Subparts C (Hazard Analysis and Risk-Based Preventive Controls) and G (Supply-Chain Program), does not apply to Fish and Fishery Products (21 CFR Part 123); Juice HACCP (21 CFR Part 120); Low Acid Canned Foods (21 CFR Part 113) in regards to microbiological hazards; Dietary Supplements (21 CFR Part 111); or Covered Produce Farms (21 CFR Part 112).*

Does your firm manufacture, process, package, and/or hold cannabis or cannabis-derived products, including cannabidiol (CBD)?

Yes No

Do you intend for cannabis or cannabis-derived products to enter into interstate commerce (transactions that cross state boundaries)?

Yes No

**Note: The Utah Department of Agriculture and Food incorporates by reference 21 CFR Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding*

Operations for Dietary Supplements for a licensee engaged in processing cannabis or cannabis-derived products.

Does your firm manufacture, process, package, and/or hold kratom or kratom-derived products?

- Yes No

Do you intend for kratom or kratom-derived products to enter into interstate commerce (transactions that cross state boundaries)?

- Yes No

**Note: The Utah Department of Agriculture and Food incorporates by reference 21 CFR Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements for a licensee engaged in processing kratom or kratom-derived products.*

General Product Categories / Type of Activity			
Check each applicable category based on the type of operation and food preparation.			
<input type="checkbox"/>	Human Food – 21 CFR Part 117	<input type="checkbox"/>	Low Acid Canned Food – 21 CFR Part 113
<input type="checkbox"/>	Dietary Supplements – 21 CFR Part 111	<input type="checkbox"/>	Juice – 21 CFR Parts 120 and/or 102 *
<input type="checkbox"/>	Infant Formula – 21 CFR Part 107	<input type="checkbox"/>	Seafood – 21 CFR Part 123 *
<input type="checkbox"/>	Acidified Food – 21 CFR Parts 114 and 108	<input type="checkbox"/>	Bottled Water – 21 CFR Part 129
<p>The owner/operator is responsible for ensuring compliance with all rules, regulations, and laws applicable to their operation.</p> <p>* A properly prepared Hazard Analysis and Critical Control Point (HACCP) plan must be submitted for validation and approval before engaging in this activity.</p>			

Please provide all requested information on the following pages. If a particular line item is not applicable to your food establishment, please indicate with "N/A".

Specifically list the type of product(s) prepared/processed on-site (i.e. bakery products, chocolate/cocoa products, cannabis, kratom, etc.); trade secrets will be treated as confidential by the regulatory authority:

Does your firm intend to prepare/process any meat, poultry, and/or siluriforme products for wholesale?

Yes No

If yes, specify the total percentage of meat, poultry, and/or siluriforme (raw and/or cooked) in each product intended for wholesale:

Indicate the anticipated daily volume of product prepared/processed and/or stored on-site; if there is more than one preparation and/or storage area, please specify the location and the anticipated volume for each area (i.e. number of commodities or packages, product weight, pallets, etc.):

Indicate the finish schedule materials (i.e. quarry tile, stainless steel, fiberglass reinforced plastic, etc.) used in each area of the food establishment (floors, walls, floor/wall junctures, and ceilings):

Ensure that manufacturer specification sheets are submitted for each piece of equipment used (including custom fabricated equipment), and ensure that all equipment is accounted for in the site plan or proposed layout.

Indicate the proposed equipment used in each area of the food establishment (including the manufacturer, model number, location, dimensions, performance capacities, and installation specifications):

The owner/operator is responsible for submitting Hazard Analysis and Critical Control Point (HACCP) plans for validation and approval before engaging in an activity that requires a management system.

This form and the provisions therein must be submitted to the Support Services Staff at udaf-estabregistration@utah.gov. Submitting this plan review application does not constitute authorization from the Utah Department of Agriculture and Food to operate a food establishment. Plans will not be reviewed until payment is received.

STATEMENT: I hereby certify that the above information is correct, and I fully understand that any deviation from the above without prior permission from the Utah Department of Agriculture and Food may delay final approval.

Printed Name: _____
Legal Agent and/or Owner

Signature: _____
Legal Agent and/or Owner

Date: ____ / ____ / ____

At least one on-site visit throughout the construction process is highly recommended as other requirements may become more apparent. A preopening inspection of the food establishment is required to determine compliance with the Utah Food Protection Rule.

For assistance completing this application, please contact the Utah Department of Agriculture and Food, Division of Regulatory Services at 801-982-2255.