Manufactured Food Establishment Plan Review Application

Division of Regulatory Services

4315 S 2700 W, TSOB South Bldg., Floor 2 Taylorsville, UT 84129-2128

Phone: (801) 982-2252; Fax: (385) 465-6023

udaf-planreview@utah.gov
https://ag.utah.gov/

Utah Department of Agriculture and Food



*Note: Not all sections of this application will apply to all facilities. If your business or building has already been permitted in the past and you are submitting for changes or expansion, please reach out to your inspector or the plan review specialist to discuss the applicable parts of the Plan Review packet that will need to be submitted. A full Plan Review may not be required. Subsequently, a lack of complete information may delay plan approval and/or the opening of your business.

Establishment Information					
	Establishment	Owner	Applicant		
	Specific location, mobile unit, etc. where product will be manufactured, sold or distributed (e.g., "Main Street Grill")	Association, corporation, individual, partnership, or other legal entity (e.g., "MSG Partners, LLC")	Person directly responsible for establishment, or local point of contact (e.g., "Jane Doe – Operations Manager" or "Architecture Firm A")		
Name:					
Physical					
Address:					
Billing					
Address:					
Phone: Indicate your preferred billing phone	Billing Phone	Billing Phone	Billing Phone		
Email:					
Billing Email:					
Owner is: Association Corporation Individual Partnership Other: Include a list (names, titles & addresses) of the persons comprising legal ownership including owners & officers; local resident agent if applicable					
Name/title/contact info of Applicant's immediate <u>supervisor</u> and/or <u>consultant</u> (e.g., regional manager, district manager, etc.) if applicable:					
Note: Consultant's and businesses operating out of a commissary kitchen must complete and submit a Letter of Authorization to the Department					

	Establishment Type	Application Type		tion Type	Dates & Times of Operation	
	Retail Food Establishment Primarily direct to consumer from this location (storefront, special order pick-up)		New Establishment		Mon. – Fri.	
	Manufactured Food Establishment Primarily wholesale & distribution		Change of	Ownership	Sat. – Sun.	
	Commissary Kitchen (LOA) Must include LOA Authorization Agreement		Change of Location		☐ Year Round	
	Warehouse – Ambient			lteration of stablishment	☐ Seasonal Anticipated Dates:	
	Warehouse – Refrigerated / Frozen					
	Pre-packaged Foods Only No open packages and no processing or repackaging occurs					
		A	dditional I	nformation		
Est	imated Date Construction Will Begin			Estimated Opening	Date:	
	al square footage: reas in the facility			Inspectable square Minus office area		
	mber of employees at location:			Number of employ		
	mber of processing areas:			Number of storage	areas:	
	icate weights & measures services: you use scanners — Yes N	0				
Do	you sell fuel – Yes No)				
Are you selling by weight or volume (variable packaging) – Yes No						
List affiliates and subsidiaries:						
Is another business involved in part of your products production (co-packer)? Yes No N/A						
If y	es, then who?					
Tel	Tell us about your distribution:					

If you need help completing this form, please contact your inspector or the Plan Review Specialist at jessicas@utah.gov or (385) 239-8355.

*Note: Prior to commencing food operations, the owner/operator must be approved for a food establishment permit and successfully pass a pre-operational inspection. UDAF requires a minimum of seven (7) calendar days' notice to schedule a pre-operational inspection. Though we will attempt to accommodate your schedule, call early to avoid scheduling conflicts and allow time for re-inspection if necessary.

Manufactured Food Establishment **Risk Assessment**

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Utah **Department**



Worksheet		https://ag.utah.gov/			UDAF
Establishment Name:		Esta	ablishment Addres	SS:	_
Product Cate	gories/Type of Activity	: Ple	ase check ea	ch applicable cate	gory
ba	ased on the type of oper	atior	n and food p	reparation.	
Human Food – 21 CFF	R 117 *		Low Acid Ca	nned Food – 21 CFR	113 & 108 **
Dietary Supplements –	21 CFR 111		Juice – 21 CF	FR 120 and/or 102 ***	
Infant Formula – 21 Cl	FR 107		Seafood – 21	CFR 123 ***	
Acidified Food – 21 C	FR 114 & 108 **		Bottled Water – 21 CFR 129 & 165		
The owner/operator is response	onsible for ensuring complian	nce wi	th all rules, reg	ulations and laws appl	licable to their
operation.	0 1			•	
•	r Acidified Foods (21 CFR 1	08 &	114); Fish and	Fishery Products (21 C	CFR 123);
	& 102); Low Acid Canned		*	,	· · · · · · · · · · · · · · · · · · ·
	ject to parts of 21 CFR 117.			- // 3 1	1
, · · · · · · · · · · · · · · · · · · ·	Acid Canned Food producer	s mus	t receive appro	val from UDAF and F	DA prior to
commencing food operation	±		Treesty Compare		DII PIIOI VO
•	zard Analysis Critical Contr	ol Poi	nt (HACCP) nl:	an must be submitted t	for validation
and approval before engagi		01101	iii (iii ieei) pi	an mast so saomitted	ioi vandanon
and approvar before engagn	ng m tms activity.				
Menu: Plea	se check each category	of fo	od that is pr	epared or used as	an
	ingredient i	in pro	eparation.		
Processing of meat, po	oultry, and/or siluriform		Dairy (cheese	, cream dessert, custar	d, ice cream)
products (raw or cooke	• .		• \	A Products <u>must</u> go through the	
Some products may also be subje	ct to USDA guidelines and/or the UDAF				
Meat Inspection program	11_	+_	G 1		
Processing of egg prod Some products may also be subje			Seed sprouts	or microgreens	
Cooked fish or seafood		+	Shelf-stable c	anned foods	

	Raw fish or seafood		Jams and Jellies			
	Raw, whole, unprocessed produce		Processed Produce (melon, cut tomatoes, fresh			
			salsa, cut leafy greens)			
	Acidified Foods (Hot sauce, dressings, etc.)		Food colors and/or additives			
	Low-acid canned foods		Oils or products held in oils			
	posed menu or complete list of food and beverage iter	ms to	be sold must be attached with the plan review			
app	lication. Product list should include:					
	Product					
	• Allergens					
	 Processing methods 					
	Packaging					
	 Storage conditions Distribution method (company dol 	•	LIDS austamar mialaum ata)			
	Distribution method (company delIntended customers	ivery	, OPS, customer pickup, etc.)			
	monaca castomers					
	Other:					
	Other					
	If your firm intends to prepare/process any meat	, pou	altry and/or siluriform products for			
	wholesale, specify the total percentage of meat,	poul	try and/or siluriform in each product			
	intended for wholesale:					
		rad				
	rtawCoor	<u></u>				
	Operations: Please check each proc	ess	or operation that is used for food			
	preparation	1 or	storage.			
	Cold holding / storage (refrigeration / freezing)		Smoking (as a method of food preservation, not just			
			for flavor) *			
	Cooking (grill, bake, fry, boil)		Curing Food *			
	Thawing		Using food or color additives *			
	Hot holding		Operating a molluscan shellfish life-support system			
	Dahaatina (nua duata that resum num num 1 - 1		tank *			
	Reheating (products that were prepared and		Packaging TCS food using a modified atmosphere			
	cooled)		packaging method (vacuum sealing) * Sprouting seeds or beans *			
	Cooling		sprouting seeds or beans *			

	Extended shelf life (expiration date of product past		Time as a public health control (in lieu of				
	7 days)		temperature control)				
	Juice (treated, pasteurized or not treated)		Modifying the food to render shelf stable *				
	Parasite destruction / record keeping (sushi, sashimi, ceviche)		Fermentation *				
	Pre-packaged food only (no processing or		Other:				
	preparation)						
	S: Time/Temperature Control for Safety Foods (a pro	duct	that requires time and/or temperature control to				
	ure food safety).						
*Tł	nis is a specialized process and requires approval before	re en	gaging in this process.				
	Does your firm manufacture, process, pa derived products, including cannabidiol	_					
	2. Do you intend for cannabis or cannabis-commerce (transactions that cross state by		-				
	3. Does your firm manufacture, process, paderived products (Mitragyna speciosa)?	_					
	4. 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 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements for a licensee engaged in processing cannabis or cannabisderived and/or kratom or kratom-derived products. Additional Utah rules apply to these products as well. Please contact UDAF's Cannabis Division at https://ag.utah.gov/industrialhempprogram/ for information relating to specific cannabis requirements. Additional information on the laws and rules associated with kratom and kratom-derived products, including product registration, can be found at https://ag.utah.gov/businesses/regulatory-services/kratom/						
	The following section must be completed by f hold food as defined in section 201(f) of the Forau materials a	edera	l Food, Drug, and Cosmetic Act (including				
	 Is your firm registered with the Food and Drug Administration (FDA) in accordance with the 2002 Bioterrorism Act? Yes No N/A 						

2.	the Fe	deral Food, Drug, and Cosmetic Act at the time of the pre-operational inspection? Yes No
3.		te your firm's average annual sales (including subsidiaries and affiliates) and/or pated average annual sales of human food:
		Greater than \$1,000,000.00 in annual gross sales (adjusted for inflation) averaged over the previous three-year period.
		Less than \$1,000,000.00 in annual gross sales (adjusted for inflation) averaged over the previous three-year period.
4.	anticip	r firm's average annual sales (including subsidiaries and affiliates) and/or pated average annual sales of human food are less than \$1,000,000.00, has your led an attestation with the FDA to become a Qualified Facility? Yes No N/A
	a.	If your firm is a Qualified Facility and intending to engage in holding / storage of 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
		ormation in regards to the FDA attestation, please see the following link: .fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility- attestation
	Subpa	te: Qualified Facilities may be exempt from some parts of 21 CFR 117, including arts C (Hazard Analysis and Risk-Based Preventive Controls) and G (Supply-Chain gram). Qualified facilities may be subject to the modified requirements of 21 CFR 117, Subpart D.
5.	are gre	r firm's average annual sales (including subsidiaries and affiliates) of human food eater than \$1,000,000.00, have you fully written and implemented a Food Safety sequired by the FDA Food Safety Modernization Act (FSMA), Preventive ols for Human Food (PCHF)? Yes No N/A

a.	. Indicate which of the following Food Safety Plan requirements you have pre 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 117, Subpart C				
		The written supply-chain program as required by 21 CFR 117, Subpart G				
		Records are maintained and established as required by 21 CFR 117, Subpart F				

*Note: Firms operating under Acidified Foods (21 CFR 108 & 114); Fish and Fishery Products (21 CFR 123); Juice HACCP (21 CFR 120); Low Acid Canned Foods (21 CFR 108 & 113) in regards to microbiological hazards; Dietary Supplements (21 CFR 111); or Covered Produce Farms (21 CFR 112) may be exempt from parts of 21 CFR 117, including Subparts C (Hazard Analysis and Risk-Based Preventive Controls) and G (Supply-Chain Program).

Manufactured Food Establishment Operational Assessment

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Utah Department of Agriculture and Food



Establishment Name:

Establishment Address:

This document is intended to assist the Utah Department of Agriculture and Food authorities responsible for the review of food establishment plans. Food establishment plan review is an important component of a food protection program that:

- Ensures food establishments are built or renovated according to the current rules and regulations;
- Enhances food safety and sanitation by promoting efficient layout and flow of food based on the menu and food preparation process; and
- Helps prevent code violations by addressing potential layout and design issues prior to construction and operations.

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".

	Food Suppliers / Vendors					
1.	1. Briefly describe your supplier program. Have you developed and implemented a program to qualify					
	suppliers? How do you source your ingredients and/or products?					
2.	Are all products sourced from commercial suppliers / vendors?					
	Food Supplies & Cold Storage					
1.	List the locations where your ingredients and finished products are stored:					
2.	Indicate the amount of space (in square feet) allocated for storage areas, if not indicated in plans or					
	drawings:					
	Dry Storage –					
	Refrigerated Storage –					

	Frozen Storage –
3.	Is adequate freezer and refrigeration available to store frozen foods frozen, and refrigerated foods at 41°F
	(5°C) or below? ☐ Yes ☐ No
4.	Will raw meats, poultry, and seafood be stored in the same refrigerators and freezers with cooked /
	ready-to-eat foods?
	If yes, briefly describe how cross contamination be prevented?
5.	Does each refrigerator / freezer have a thermometer located in the warmest area of the unit (e.g., near the
	door)?
	Describe your methods and frequency of temperature monitoring?
6.	Is there a bulk ice machine available?
	If yes, describe the method and frequency that this machine will be cleaned and sanitized?
7.	Briefly describe how dry goods will be stored:
	Food Labeling & Packaging
1	*Shelf life of products past 7 days may require scientific validation, testing and/or process authority approval For firms that are processing, packaging, and/or repackaging foods, please briefly describe your product
1.	packaging and methods and include a representative sample of your labels:
	packaging and methods and metade a representative sample of your labels.
2	If your products have extended shelf-life (beyond 7 days), please indicate the shelf-life of your products
2.	and submit the information used to support the safety of these products during the extended shelf-life:
3.	If pH, Aw, or other methods are used as safety measures, please briefly describe your monitoring,
	documentation, and calibration methods and frequency:
	Facility Practices
1.	Briefly describe how your food employees be trained in good food sanitation practices (policies and/or
	methods, and frequency):

2.	Does your firm handle or produce ready-to-eat foods that are exposed to the environment prior
	packaging?
	Briefly describe your environmental monitoring program:
3.	Briefly describe how equipment, utensils, and other food contact surfaces will be sanitized, including
	methods:
	Frequency:
	Chemical type: Concentration:
	Available test kit: Yes No
4.	Briefly describe your employee health policy to restrict food workers who are sick or who have infected
	cuts or lesions:
5.	Briefly describe your allergen control plan (when allergens are present in the facility and vary among
	products):
6.	Briefly describe your recall plan including documentation and how it meets the requirements of 21 CFR
	117.139:
7.	Do you conduct lot coding? Yes No
	Briefly describe your lot coding:
8.	Indicate the anticipated daily volume of food prepared, processed and/or stored on site (e.g., number of
	commodities or packages, product weight, pallets, etc.):
9.	Briefly describe storage facilities for employee's personal belongings (e.g., purse, boots, hat, etc.):
10.	Briefly describe how linens will be laundered and stored:
	Thawing, Cooking & Reheating
*If these	processes do not occur at your facility, indicate N/A and move on to the next section \square N/A

1. Briefly describe your thawing methods (including placement and duration) (i.e., chicken is thawed in							
in o	in cooler on the bottom shelf for 2 days before preparation):						
Ur	Under refrigeration:						
Ot	her:						
Le							
2. Br	Briefly describe your cooking and cooling procedures (if applicable):						
3. De	Describe the methods and equipment used to verify final cooking or reheating temperatures:						
W	ith wha	at type of temperature measuring device	e?				
Но	ow are t	temperature measuring devices calibrat	ed and at what frequency?				
	Spacifi	Equipm	nent List standard kitchen equipment manufactured in the U.S.)				
	Бресіјі	Major Equipment	Model Numbers				
		Interior Fin	ish Schedule				
			oors				
All floor/	wall jur		storage areas, warewashing areas and toilet rooms must ealed				
Food	1						
Product							
Area(s	/						
	. ,						
Food Sto Area(s	_						
Ware War	/						
Area(s	\sim						
			alls unable, durable and non-absorbent				
Food							
Product Area(s							
Toilet Roo	_						

Food Storage								
Area(s)								
Ware Washing								
Area(s)								
	Ceiling	gs must be sm		<mark>eilings</mark> • cleanable, d	urable and non-poroi	us		
Food								
Production								
Area(s)								
Toilet Room(s)								
Food Storage								
Area(s)								
Ware Washing								
Area(s)								
	Т	Wa		Vaste Dis		2 (2)		
			Water		Waste (Sewer / Septic)		
Public (Na	ame)	I.e.	- SLC municipal	i water				
Private (T	ype)		I.e private well					
Trash Dist	posal							
Number, size & freque								
Grease Stor	age (if							
applicab	• ,							
Location &	/							
1. Is there a	water treatm	ent device?	Yes [] No				
If yes, br	iefly describe	the treatmen	t and how t	he device wil	ll be inspected & serv	iced:		
2. Describe	method and	frequency of	grease traps	s inspected &	serviced, if applicabl	e:		
Backflow Prevention								
			Air Gap	Air Break	Vacuum Breaker	Other		
Dishwasher(s)								
Ice Machine(s)								
Mop Sink(s)								
	mpartment S							
Refrigeration C	rain Line(s)							

Chemical Dispenser(s)				
Vending Machine(s)				
Other				
Briefly describe method and frequence	ency of how	backflow pro	evention devices are	inspected & serviced:
	Pest	Control		
Briefly describe your pest control p	program:			
2. Briefly describe how you will main	ntain the are	a around the	building:	
a specialized processing method. This form and the provisions the udaf-planreview@utah.gov. Suldoes not constitute an authoriza operate a food establishment. Planter of the statement of the st	bmitting thi tion from tl lans will not	is food estab he Utah Dep t be reviewed	lishment plan revious artment of Agricul luntil payment is i	ew application ture and Food to received.
any deviation from the above with and Food may delay final approva	nout prior pe			-
Printed Name:	Legal Aş	gent and/or C	wner	
Signature:	Legal Aş	gent and/or C	wner	
Date: / /				