

## SMALL FOOD PROCESSOR PREPAREDNESS: DOCUMENTATION REQUIREMENTS, REGULATORY COMPLIANCE, AND FOOD SAFETY

PCHF RULE QUALIFIED EXEMPTION-  
ELIGIBLE FOOD FACILITIES



### REGULATORY LANDSCAPE

- Just because we're focusing on COVID-19 preparedness, doesn't mean the existing regulations matter less
- During times of uncertainty and potential disruption in food production chains, production of safe product that complies with regulations is even more important
- Many of the practices that support COVID-19 preparedness (GMPs, business continuity plans) also enhance preparedness and compliance with food safety regulations
- More purchasing of retail sales, interest in local foods. For new and existing businesses, now is a valuable time to strategize about what you need to do to bring new products to market. This means identifying the steps to get food safety documentation in place and training completed.



FDA FOOD SAFETY  
MODERNIZATION ACT

REGULATIONS  
WE ARE  
DISCUSSING

- How does this pertain to smaller food processors?
  - Who is subject to what aspects of the regulation
- What programs need in place to be compliant?
- What documentation needs to be in place to be compliant?

### WHO REGULATES FOOD?



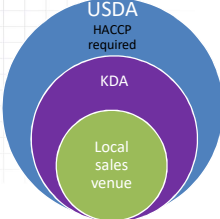



- State level inspectors
- "Cottage food"

- Most food
- Seafood
- Dairy
- Shell eggs
- Juice
- Acidified and low acid canned foods

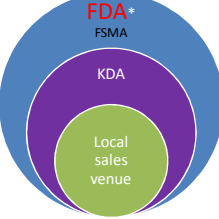
- Meat
- Poultry
- Egg products

Selling meat and poultry?





Note- includes products where raw meat or poultry comprises >3% total product weight or 2% meat by cooked weight.

Selling any other food- Kansas



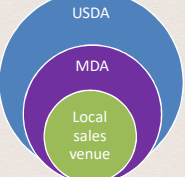
\*HACCP currently required for juice, seafood

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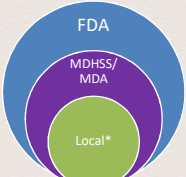
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Selling (fresh) meat and poultry?



Note- includes products where raw meat or poultry comprises >3% total product weight or >2% meat by cooked weight.

Selling any other food- Missouri



\* See next slide

MO cities with food ordinance:

- St Joseph
- Kansas City
- Independence
- Joplin
- Branson
- Springfield
- Marshall
- Boonville
- Columbia
- Fulton
- St Pierre
- St Louis City
- Jefferson City
- Rolla
- West Plains
- Poplar Bluff

As of Jan 2015

**Food Ordinances**

- Cities with Food Ordinance (city inspectors perform inspection under local authority) 23
- State Authority (Local Public Health Agency inspectors perform inspections under state authority) 79
- County Ordinances (Local Public Health Agency inspectors perform inspections under local authority) 36

## Kansas regulations

- KS Dept of Ag regulates food products sales in KS
- In KS, regulations are the same statewide
  - MO: regulations may vary by county, city
  - Sales in other states- check their regs, follow [FDA/USDA regs](#)
- Individual sales venues may have stricter requirements

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## KSRE/KDA regulations publication

- KS "Farmers Market" publication covers all food sold direct to consumers (D2C)
  - This generally includes products sold online also
  - Includes fairs, fundraisers, craft shows, etc. also

[www.ksre.ksu.edu/bookstore/Item.aspx?catid=201&pubid=17219](http://www.ksre.ksu.edu/bookstore/Item.aspx?catid=201&pubid=17219)

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NOT allowed (*WITHOUT proper licensing*)-  
KS, D2C

- Home canned pickles, meats, vegetables, sauerkraut
- Home baked cream or meringue pies, custards, cheesecakes, cream-filled cupcakes, cream cheese frostings, etc. (need temp. control for safety)
- Home-made dairy products (cheese, yogurt, etc.)
- Uninspected meat

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## Foods allowed WITHOUT licensing-KS, D2C

(do NOT need to be labeled "homemade"- but can be)

- Home baked goods (cookies, breads, cakes, etc)
- Dry baking mixes
- Fresh or dried uncut fruits, vegetables and herbs
- Certain cut produce and cut herbs (dried or fresh)
  - Cut tomatoes, melons, leafy greens require a license
- Microgreens and shoots (not cut beyond normal harvesting)
- \*Other lower risk foods- listed in publication

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## Foods that require testing first- KS

- Why do we need to test some food?
  - Every formulation of some products may be different
  - Need to be sure food is safe
- *Products can be sent to Fadi Aramouni lab or other accredited lab*

[www.ksre.ksu.edu/kvaf/](http://www.ksre.ksu.edu/kvaf/)

Alkaline pH	11	Ammonia
	10	Soap
	9.0	
	8.0	Egg whites
	7.0	Water
Neutral pH	7.0	Milk
	6.0	Meat
	5.0	Melons
	4.0	Cheese
Acidic pH	3.0	Vegetables
	2.0	Bread
	1.0	Tomatoes
	0.0	Fruits/Jams
	-1.0	Orange juice
	-2.0	Pears
	-3.0	Plums
	-4.0	Vinegar
	-5.0	Lemon/Lime

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### How to get the license needed- KS?

- Visit the KDA website <http://agriculture.ks.gov/divisions-programs/food-safety-lodging/food-safety-egg-lodging-app-forms>
- or email [fsl@kda.ks.gov](mailto:fsl@kda.ks.gov)
- or call 785 296 5600

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### MO regulations

MDHSS Bureau of Environmental Health Services

- **Retail foods direct to consumers** (farmers markets vendors, restaurants, retail store, etc must follow)
  - MO Food Code- updated to 2009 FDA Code in 2013
- **Food processors** (those not selling direct to consumers):
  - MO Statutes 196: Food, Drugs, Tobacco; 192: DHSS
  - No state licensing/initial registration required; but processor must be in compliance with regulations
  - State can shut down, has right to inspect

<http://health.mo.gov/safety/foodsafety/>

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### MU Regulations for Selling Safe Canned Foods in Missouri Fact Sheet:

- <https://extension2.missouri.edu/n1304>



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### MO State regulations-1

Product	License required
Breads, cookies, fruit pies, inshell nuts, sorghum, packaged spices & spice mixes, dry mixes (cookie, cake, bread, soup), etc.	Direct sales only: no license, labeled as "not inspected"
Fruit jams and jellies, preserves, fruit butters, honey, maple syrup, dry pasta, coffee, dried fruits	consumer direct: no license, labeled "not inspected", sign
LOW SUGAR fruit jams and jellies	testing required; pH <4.0- none; pH 4.0-4.6: license; pH >4.6: low acid

\*Regulations for other canned foods listed in publication

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Product	Requirements
Cider	Can be sold direct to consumer from farm raw; otherwise, HACCP plan required
Cheesecakes, cream or meringue pies, custards	For any baked products requiring refrigeration for safety, license required
Milk and dairy products	MDA Milk Board inspected; raw milk can only be sold on farm; temp control
Bottled water	FDA and State regs
Fresh whole produce	May be covered by FDA FSMA; GAPs or other certification is buyer driven
Microgreens	Must comply with FSMA if required.
Poultry and rabbits	If <1000 carcasses/year, can sell at farmers market (and restaurants and institutions) without inspection (slaughter on own farm); must stay in state. Proper temps.

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Product	Requirements
Beef, pork, other meats	Must be inspected (USDA or MDA), have mark of inspection; kept at proper temp
Wild game	Wild game may NOT be sold at a farmers market; commercially raised must follow same requirements as beef and pork
Eggs- chicken, turkey, duck, goose, guinea	MDA egg license. Eggs should be clean, name and address of producer on carton, <45F
Prepared foods (food service)	Hand and ware washing facilities; hot/cold food holding; safe water (hot and cold) supply; Protected from contaminants
Sprouts, wild mushrooms	Sprouts- inspected facility; mushroom expert ID required

### Selling to grocery stores, wholesalers, etc- KS or MO?

- **Licensing is required for ALL products sold retail/ wholesale, other than**
  - Fresh uncut fruits, vegetables and herbs
  - Intact salad greens
  - *Cultivated whole* mushrooms (fresh)

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### Additional information- KS

- Kansas Department of Ag Food Safety and Lodging
  - <http://agriculture.ks.gov/divisions-programs/food-safety-lodging>
- KS Value Added Foods Lab (KVAFL- scheduled processes, product testing, nutrition facts)
  - [www.ksre.k-state.edu/kvaf/](http://www.ksre.k-state.edu/kvaf/)
- KSU Extension Food Safety website
  - [www.ksre.k-state.edu/foodsafety/](http://www.ksre.k-state.edu/foodsafety/)

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### Additional information- MO

- MO Dept of Health and Senior Services
  - <http://health.mo.gov/safety/foodsafety>
    - Includes brochure on jams and jellies
- MDHSS food processor requirements
  - [http://health.mo.gov/safety/foodsafety/pdf/Processor\\_Brochure.pdf](http://health.mo.gov/safety/foodsafety/pdf/Processor_Brochure.pdf)
- MO Dept of Ag
  - <http://agriculture.mo.gov/>

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### Contact Details

Londa Nwadike

Extension Consumer Food Safety Specialist  
Kansas State University/ University of Missouri

Phone: 913 307 7391/ 816 482 5860  
Email: [Inwadike@ksu.edu](mailto:Inwadike@ksu.edu)  
<http://www.ksre.ksu.edu/foodsafety/>  
<http://missourifamilies.org/foodsafety/newsletters/>


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PRODUCT EXAMPLE – WHAT ARE THE REGULATIONS?



FSMA?  
Acidified foods?  
Cottage foods?

PRODUCT EXAMPLE – WHAT ARE THE REGULATIONS?



FSMA?  
Low Aw (canned) food?  
Cottage foods?

## WHAT DO I HAVE TO DO?

### It Depends!

Food safety risks (severity and likelihood of illness or injury to consumers) influenced by:

- Types and sources of ingredients
- Packing and distribution
- Consumers
- Facility size

You may be subject to one or more regulations with different requirements, basis for exemption, and documentation requirements.

## FOOD SAFETY MODERNIZATION ACT

Subpart A – General Provisions  
 Subpart B – Current Good Manufacturing Practice  
 Subpart C – Hazard Analysis and Risk-based Preventive Controls  
 Subpart D – Modified Requirements  
 Subpart E – Withdrawal of a Qualified Facility Exemption  
 Subpart F – Requirements Applying to Records That Must be Established and Maintained  
 Subpart G – Supply-chain Program



- Human Food
- Produce Safety
- Animal Feed and Pet Food
- (etc...)

## FOOD SAFETY MODERNIZATION ACT

### Subpart C – Hazard Analysis and Risk-based Preventive Controls

- Written hazard analysis
  - Process preventive controls
  - Sanitation preventive controls
  - Allergen preventive controls
- Subpart G – Supply-chain Program**
- Supply chain preventive controls



- Human Food
- Produce Safety
- Animal Feed and Pet Food
- (etc...)

## PREVENTIVE CONTROLS FOR HUMAN FOOD

Subpart A – General Provisions  
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- Human Food
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- (etc...)

## GMPS ARE REQUIRED

- The current federal GMP regulation specifically applies to all food products regulated by FDA.
- It outlines the basic sanitary controls that are required for all food processing plants, wholesale or food distribution firms and food storage facilities that handle, store or process FDA-regulated food. This GMP regulation also provides a framework for the specific state regulations that may apply to these firms.

## A REVIEW OF SOME TERMS

- **Food Safety** – programs or activities that serve to prevent illness or injury that results from eating food
- **Hazards** – the things that cause illness or injury
- **Risk** – the likelihood of illness or injury occurring

Different food safety programs (and regulations) address the issues of hazard and risk in different ways. Our goal in this module is to: (1) identify pertinent hazards specific to you and (2) consider relevant food safety activities to manage those risks outside of Preventive Controls

## IMPACTS

- Contaminated food that makes you sick
- Foodborne illness, foodborne disease, or food poisoning
- 48 million cases of foodborne disease**
  - 1:6 people in the US each year
  - Quality of life
- 3,000 deaths**
- 128,000 hospitalizations**
- Economic burden**
  - Missed work days
  - Recalled product
- Caused by biological hazards: pathogenic bacteria, viruses, and parasites



Scallen, 2011

## HAZARDS

Has the potential to cause illness or injury in the absence of an appropriate control

Types of hazards:

- Biological
- Chemical
- Physical



## COMPONENTS OF GOOD MANUFACTURING PRACTICES (GMPs)

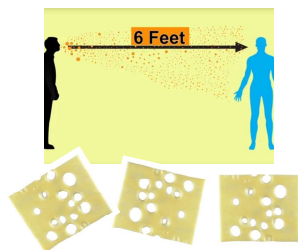
- The regulation (21 CFR 117 Subpart B) lists these components that establish the conditions and practices the food industry must follow for processing safe food under sanitary conditions:
  - Personnel
  - Plant and grounds
  - Sanitary operations
  - Sanitary facilities and controls
  - Equipment and utensils
  - Processes and controls
  - Warehousing and distribution
  - Holding and distribution of human food by-products for use as animal food, and

## PERSONNEL

- Restricting persons with illness or open wounds
- Proper handwashing and sanitizing
- Adequate personal cleanliness
- Suitable gloves maintained in satisfactory condition
- Suitable outer garments
- Jewelry removed
- Hair restraint
- Personal items stored away from production areas
- No eating, drinking or tobacco use in production area

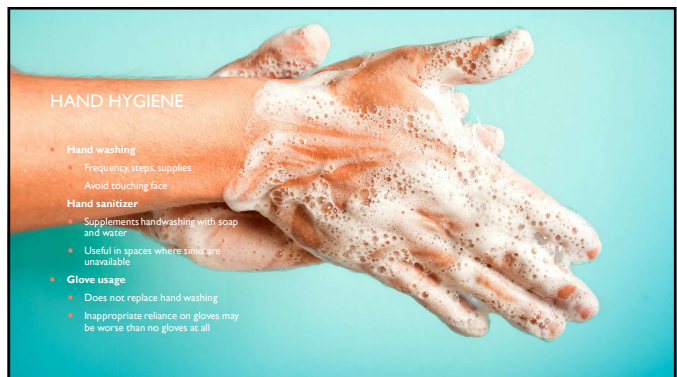
## SOCIAL DISTANCING IS STILL (ALWAYS) IMPORTANT

- People are the source of virus particles
- Additional measures, such as mask usage and surface sanitation can help, but do not replace the need for social distancing



## HAND HYGIENE

- Hand washing**
  - Frequency, steps, supplies
  - Avoid touching face
- Hand sanitizer**
  - Supplements handwashing with soap and water
  - Useful in spaces where sinks are unavailable
- Glove usage**
  - Does not replace hand washing
  - Inappropriate reliance on gloves may be worse than no gloves at all



### PLANT AND GROUNDS

- Removal of debris, unused equipment and uncut vegetation
- Proper drainage of grounds
- Proper waste disposal
- Adequate space for operations and cleaning
- Proper separation of operations to prevent cross-contamination and allergen cross-contact
- Cleanable walls, floors and ceilings kept in good repair
- Prevent drip or condensate from contaminating the product
- Adequate lighting
- Guard against glass breakage
- Adequate ventilation that does not contaminate the product
- Screened openings to the outside

### SANITARY OPERATIONS

- Plant maintained in good state of repair
- Cleaning operations not a source of contamination
- Cleaning and sanitizing compounds safe and free from contamination
- Unnecessary toxic chemicals not stored
- Toxic chemicals properly identified, stored and used**
- Pest control safe and effective**
- Food-contact surfaces cleaned and sanitized before use and after interruptions**
- Non-food-contact surfaces cleaned as necessary
- Single service articles protected from contamination
- Recontamination of portable equipment and utensils prevented

### SANITARY FACILITIES AND CONTROLS

- Adequate potable water supply
- Proper plumbing
- Adequate floor drainage
- Proper sewage disposal
- Adequate, accessible, sanitary toilet facilities**
- Convenient hand-washing and sanitizing facilities**
- Proper trash and waste disposal

### SANITIZERS THAT CAN BE USED TO CONTROL COVID-19


- The sanitizer you use for common spaces does not need to be "wine sensitive"
- How do you know the the sanitizer is effective against coronavirus?
  - Check if the EPA registration number listed on the product label
  - See if number is on EPA List N
  - List N sanitizers are active against SARS-CoV-2



<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>

### HOW TO KNOW IF DISINFECTANTS ARE APPROVED FOR USE AGAINST NOVEL CORONAVIRUS

Find the EPA Registration Number on the product label




EPA Reg. No. 6836-349-1677

Base Registrant Company Number | Product Number | Sub-Registrant Company Number

To verify your product is on the list of [EPA registered antimicrobial products for use against novel coronavirus](#), match the first two parts of the EPA Registration Number.

Note: Searching by product or company name will not yield full approved list.

List N Disinfectants for Use Against SARS-CoV-2



EPA list of registered antimicrobial products for use against novel coronavirus, the cause of COVID-19.

### PROCESSES AND CONTROLS

#### RAW MATERIALS AND INGREDIENTS

- Comply with FDA requirements for pests, extraneous material or undesirable microorganisms, as assured by testing, supplier certification or heat treatment
- Inspect for suitability
- Store and handle to prevent contamination and deterioration
- Properly identify rework and prevent contamination, allergen cross-contact and deterioration

### PROCESSES AND CONTROLS MANUFACTURING OPERATIONS

- Prevent microbial growth through:
  - Cooking, time/temperature control, water activity control, pH etc.
- Use clean and sanitized equipment, utensils and finished product containers
- Manufacture ice from potable water in a sanitary manner
- Prevent cross-contamination and allergen cross-contact

### HOW HAVE GMPS BEEN MODERNIZED

**Increased emphasis on allergen management**

- This includes issues relating to sanitation and cleanliness to prevent cross-contact
- Transfer of allergens from shared utensils and equipment
- Order of food produced in the facility
- Receipt and storage of allergens
- If you're in a shared-use facility, how do you manage risks posed by others? If you use a co-packer, do you know their policies on allergen management?

### Wear masks, social distance/reduce capacity, increase ventilation

#### How to Align Meatpacking and Meat Processing Workstations, if Feasible

**Bad:** Workers are within six feet of one another, including at side-by-side or facing workstations.

**Good:** Physical barriers, such as partitions, separate workers from each other.

**Good:** Workers are spaced at least six feet apart, not facing one another. Other configurations may be used to achieve similar distancing between workers.

**Good:** Physical barriers, such as partitions, separate workers from each other, including where workers need to perform tasks in tandem across from one another.

- 6 ft. spacing; wearing PPE
- Employees facing in same direction
- Use of physical barriers in one or both directions to separate employees

<https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/meat-poultry-processing-workers-employers.html>

### REGULATION

#### Subpart A – General Provisions

#### 21 CFR 117.4 Qualifications of individuals who manufacture, process, pack or hold food

- (a) **Applicability.** (1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.
- (2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject to subpart C, D, E, F, or G of this part are qualified to perform their assigned duties.
- (b) **Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food.** Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:
  - (1) Be a qualified individual as that term is defined in 117.3—i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and
  - (2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.

### HOW FREQUENTLY DO THEY NEED TO BE TRAINED?

Facility size (number of employees)	Not required	Once every 4+ years	Once 2-3 years	Once per year	More than once per year
1 to 2	0	0	0	0	0
3 to 10	0	0	0	0	0
11 to 30	0	0	0	0	0
30+	0	0	0	0	0

- Regulation only states that they must be qualified and receive training, does not establish frequency for refresher training
- Optional rule of thumb:
  - Whenever an employee's responsibilities change
  - Whenever an issue solvable by training is identified
  - At least once a year

### WHAT TYPE OF TRAINING SHOULD THEY RECEIVE

- Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.
- Could be delivered by:
  - Instruction by supervisor
  - Extension courses
  - Online classes
- Tradeoffs regarding cost, time, and quality of instruction exist for each training method and options
- Resources for GMP training provided in subsequent slides



## RESOURCES - ONLINE

- <https://instituteforfoodsafety.cornell.edu/trainings/good-manufacturing-practices-registration/>
  - Module 1: GMP Regulation & Training
  - Module 2: Food Safety: Microbes & Allergens
  - Module 3: Personnel: Health & Hygiene
  - Module 4: Plant Grounds & Pest Control
  - Module 5: Plant Construction & Design
  - Module 6: Sanitary Facilities: Water, Plumbing & Toilets
  - Module 7: Sanitary Operations: Cleaning & Sanitizing
  - Module 8: Equipment & Utensils
  - Module 9: Plant Operations & Raw Materials
  - Module 10: Manufacturing Operations: Process Controls
  - Module 11: Warehousing, Food Disposition & Defects
  - Module 12: Building Sanitation Procedures
- Various online certificate programs
  - Can be completed over multiple sessions from remote locations

## DOCUMENTATION

**Records. Records that document training required must be established and maintained.**

- What information is useful to keep on a training log?
  - Title of the record, facility name, etc.
  - Name of the employee trained
  - Date of the training
  - Signature or initials of trainer or supervisor
  - Type or content of the training (e.g. GMPs, HACCP thermal processing, etc.)

## EXAMPLE DOCUMENTATION

Facility Name: ABC Food Company  
Record Title: Employee Training Log  
Last updated: December, 2018

Employee Name	Title	Date of Training	Training Type	Supervisor Signature
Bob Jones	Shift manager	November 2018	PCQI	<i>B. Jones</i>
Candace Doe	Line operator	December 2018	GMPs	<i>B. Jones</i>
Sheryl Cutter	Warehouse supervisor	December 2018	GMPs	<i>B. Jones</i>
Jerome Cup	Pasteurizer operator	December 2018	GMPs	<i>B. Jones</i>
Lisa Marie	Business owner	December 2018	GMPs	<i>B. Jones</i>
Travis Mark	QA Technician	December 2018	GMPs	<i>B. Jones</i>

## FOOD SAFETY MODERNIZATION ACT

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Subpart G – Supply-chain Program



- **Human Food**
- **Produce Safety**
- **Animal Feed and Pet Food**
- (etc...)

## REGULATION CANNOT BE ONE SIZE FITS ALL

- No food facility is exempt from the responsibility to produce safe food
- However, different scales and types of supply chains pose varying levels of risk to public health
- One of the parts of this risk-based, scale-sensitive approach was a provision that set forth modified requirements for very small businesses

## PCHF REQUIREMENTS FOR A QUALIFIED FACILITY

- Subject to modified requirements in 21 CFR Part 117.201 of the Preventive Controls for Human Food Rule
- These modified requirements require the business to submit a form to FDA, attesting to its status as a qualified facility

### ELIGIBILITY TO BE A QUALIFIED FACILITY

1. "Very Small Business"
  - Less than \$1 million in annual sales (or the value of food you hold, manufacture, or distribute) of human food, OR
2. Less than \$500,000 in annual gross sales (adjusted for inflation) over a previous three-year period AND sells the majority of the food directly to a "qualified end-user"
  - "Qualified end-user": i.e., a consumer, or a restaurant or retail food establishment (e.g., a grocery store) that is located in the same state as the facility or not more than 275 miles from the facility)

### QUALIFIED FACILITIES ARE SUBJECT TO 5 PARTS OF THE PCHF RULE

1. General provisions
2. Current Good Manufacturing Practices
3. Modified requirements that apply to a qualified facilities
4. Certain recordkeeping requirements
5. Withdrawal of modified requirements that apply to qualified facilities

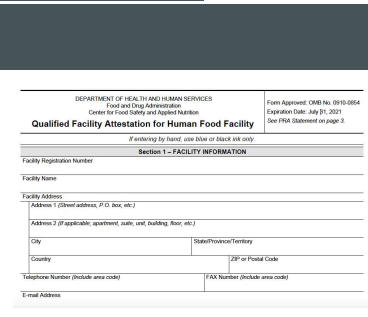
### DOCUMENTATION REQUIRED FOR QUALIFIED FACILITIES

- Under the modified requirements, qualified facilities must submit two types of documentation to FDA:
  1. A statement from the qualified facility certifying that it is a qualified facility
  2. Either:
    1. Documentation showing that the facility has identified hazards, is implementing preventive controls, and is monitoring to ensure the effectiveness of the preventive controls; OR
    2. Documentation that the facility is complying with applicable non-Federal food safety law (e.g., state, local, or county)

### FDA BIOTERRORISM REGISTRATION (BT REGISTRATION)

- BT registration requirements existed prior to FSMA – you may already be registered!
- If you are not required to BT register, you are not subject to subpart C and G of the PCHF rule
  - Still subject to GMPs either way
- If you do BT register, the business size calculation may qualify you for an exemption from subparts C and G
- Who does not have to BT register?
  - Farms
  - Food service
  - Retail establishments
- To register, use Form FDA 3537 available through the same portal as the qualified facility attestation through the "FDA Industry Systems"
 

<https://www.access.fda.gov/>



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Form Approved OMB No. 0910-0854  
Expiration Date: July 31, 2021  
(See FDA Statement on page 2)

**Qualified Facility Attestation for Human Food Facility**

(If completed by hand, use form FD-3942A-010)

**Section 1 – FACILITY INFORMATION**

Facility Registration Number \_\_\_\_\_

Facility Name \_\_\_\_\_

Facility Address \_\_\_\_\_

Address 1 (Street address, P.O. box, etc.) \_\_\_\_\_

Address 2 (If applicable, apartment, suite, unit, building, floor, etc.) \_\_\_\_\_

City \_\_\_\_\_ State/Province/Territory \_\_\_\_\_

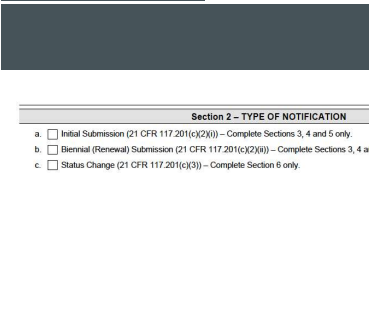
County \_\_\_\_\_ ZIP or Postal Code \_\_\_\_\_

Telephone Number (include area code) \_\_\_\_\_ FAX Number (include area code) \_\_\_\_\_

E-mail Address \_\_\_\_\_

**COMPLETING THE ATTESTATION FORM**

**(FDA 3942A)**



**Section 2 – TYPE OF NOTIFICATION**

a.  Initial Submission (21 CFR 117.201(c)(2)(i)) – Complete Sections 3, 4 and 5 only.

b.  Biennial (Renewal) Submission (21 CFR 117.201(c)(2)(ii)) – Complete Sections 3, 4 and 5 only.

c.  Status Change (21 CFR 117.201(c)(3)) – Complete Section 6 only.

**COMPLETING THE ATTESTATION FORM**

**(FDA 3942A)**

**Section 3 – QUALIFICATION FOR MODIFIED REQUIREMENTS** (Fill out only if Section 6 does not apply.)

Human food facilities may be exempt from the preventive controls regulations in 21 CFR part 117, primarily in subparts C and G, with associated requirements in subparts A, O, E, and F, under 21 CFR 117.5(a). Check the appropriate box to indicate the reason why your facility is a qualified facility.

When including the sales by any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate:

The above named facility qualifies for the exemption as a "very small business" as defined in 21 CFR 117.3 because, during the preceding three calendar years, the facility (including any subsidiaries and affiliates) averaged less than \$1,000,000, adjusted for inflation, per year, in sales of human food (plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for sale)).

The above named facility qualifies for the exemption as a "qualified facility" as defined in 21 CFR 117.3 because:

(1) during the preceding three calendar years, the average annual monetary value of the food manufactured, processed, packed, or held at the facility that was sold directly to qualified end-users (as defined in 21 CFR 117.3) exceeded the average annual monetary value of the food sold by the facility to all other purchasers; and

(2) the average annual monetary value of all food sold during the preceding three calendar years was less than \$300,000, adjusted for inflation.

**COMPLETING THE ATTESTATION FORM**  
(FDA 3942A)

**Section 4 – COMPLIANCE WITH 21 CFR 117.201** (Fill out only if Section 6 does not apply.)

Check the box to indicate how your facility is in compliance with 21 CFR 117.201(a)(2).

I, as the owner, operator, or agent in charge of the above-named facility, (1) have identified the potential hazards associated with the food being produced, (2) am implementing preventive controls to address the hazards, and (3) am monitoring the performance of the preventive controls to ensure that such controls are effective. (21 CFR 117.201(a)(2)(i)) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(b))

The above named facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law including relevant laws and regulations of foreign countries. This is based on my knowledge, as the owner, operator, or agent in charge of the above-named facility, of the facility's licenses, inspection reports, certificates, permits, credentials, certification (or an appropriate agency (such as a State department of agriculture), or other evidence of oversight. (21 CFR 117.201(b)(2)(ii)) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(b))

**COMPLETING THE ATTESTATION FORM**  
(FDA 3942A)

**Section 5 – ATTESTATION STATEMENT** (Fill out only if Section 6 does not apply.)

I attest that, to the best of my knowledge and belief, the information provided in this Qualified Facility Attestation is true, accurate and complete and that the above-named facility qualifies for the exemption requested. I understand that, as the owner, operator, or agent in charge of the above-named facility, I must maintain those records relied upon to support these attestations (21 CFR 117.201(b)) and make those records promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request (21 CFR 117.300). I also understand that under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name and Title: \_\_\_\_\_

Please check one option below that best describes your relationship to the facility.

Owner  Operator  Agent in Charge

Please provide your contact information below if it differs from the facility information provided in Section 1.

Contact Address: \_\_\_\_\_  
Address 1 (Street address, P.O. box, etc.): \_\_\_\_\_

**COMPLETING THE ATTESTATION FORM**  
(FDA 3942A)

**WILL THE FDA DETERMINE IF MY FACILITY IS A QUALIFIED FACILITY?**

**NO**

- You are responsible for determining whether your business meets the definition of a qualified facility
- Subject to verification by FDA

**FDA CAN REVOKE QUALIFIED FACILITY STATUS**

- FDA can withdraw a qualified exemption under certain broad circumstances:
  - Foodborne illness outbreak linked to a qualified facility
  - Necessary to protect the public health and prevent or mitigate a foodborne illness outbreak
    - FDA discretion following an inspection
    - Based on conduct or conditions associated with the facility

**CALCULATION TO DETERMINE QUALIFIED FACILITY STATUS**

- How often do I need to do this calculation?
  - Each year
  - No later than July 1 of each calendar year (21 CFR 117.201(c)(1)).

### CALCULATION TO DETERMINE QUALIFIED FACILITY STATUS

- Include ALL human food
- Regardless of whether the human food is subject to the PCHF Rule
  - Foods subject to HACCP regulations
    - juice, seafood
  - Food subject to other regulations
    - low acid canned foods, dietary supplements
  - Raw Agricultural Commodities (RACs)
    - produce, grains, milk, eggs
  - USDA regulated products
    - meat, poultry

### HOW DO I CALCULATE MY AVERAGE ANNUAL SALES?

- Determine which three years to include in the average
- Determine annual sales and market value of food manufactured, processed, packed, or held without sale for each of the three years
- Adjust annual sales and market value for each year for inflation
- Calculate the inflation-adjusted average annual sales and market value

### WHAT YEARS DO I USE IN MY CALCULATION?

- Average is based on the 3-year period preceding the applicable calendar year
- The applicable calendar year is the current year
- If the current year is 2019, the three preceding calendar years would be 2016, 2017 and 2018

### WHAT IF I DO NOT HAVE 3 YEARS OF FINANCIAL RECORDS FOR MY CALCULATION?

- The compliance date for you to keep records to support your status as a qualified facility is January 1, 2016
  - The compliance date for you to begin complying with the modified requirements for a qualified facility is September 17, 2018.
  - FDA intends to accept records for the preceding 2 calendar years as adequate to support status as a qualified facility.
- If you begin operations between January 1, 2017, and September 17, 2018, your applicable financial records would not cover even 2 calendar years by September 17, 2018.
  - FDA intends to accept records for the preceding one or two years as adequate to support your status as a qualified facility until you have been in operation long enough to provide three years of records.
- If you begin operations after January 1, 2018, you can rely on a projected estimate of revenue (or market value) at the time you begin operations.
  - FDA intends to evaluate the credibility of the projected revenue (or market value) based on such factors as your number of employees

### HOW DO I ADJUST ANNUAL SALES PLUS MARKET VALUE OF HUMAN FOOD PRODUCTS FOR INFLATION?

- Use the U.S. Bureau of Economic Analysis' Implicit Price Deflators for Gross Domestic Product (GDP)
- Adjust using the 2011 Implicit Price Deflator as the baseline

$$\begin{array}{c}
 \text{Annual sales +} \\
 \text{market value of} \\
 \text{food held}
 \end{array}
 \times
 \begin{array}{c}
 \text{2011 implicit} \\
 \text{price deflator} \\
 \text{index number}
 \end{array}
 =
 \begin{array}{c}
 \text{Inflation-} \\
 \text{adjusted sales} \\
 \text{plus market} \\
 \text{value}
 \end{array}$$

$\div$ 
 $\begin{array}{c} \text{Current year implicit} \\ \text{price deflator number} \end{array}$

### WHAT IF I SUPPLY INGREDIENTS TO A PROCESSOR WHO IS NOT A QUALIFIED FACILITY?

- Do you control a hazard for that processor?
  - For example, you sell chocolate to a granola bar manufacturer. The granola bar manufacturer does not apply a baking step to kill pathogens and relies on you to ensure the chocolate does not contain *Salmonella*.
- The receiving facility (granola bar manufacturer) must obtain written assurance that a supplier is a qualified facility before first approving the supplier for an applicable calendar year, and on an annual basis thereafter; by December 31 of each calendar year, for the following calendar year (21 CFR 117.430(c)(1)). Note that the receiving facility must obtain other written assurances from the supplier every two years.

### WHAT OTHER EXEMPTIONS FROM C AND G EXIST?

- Alcoholic beverages
- Retail/food service
- 501 3C
- Description can be found in 21 CFR 117.5
  - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=117.5>

### RECORD KEEPING REQUIREMENTS

- A qualified facility must maintain records that support the documentation required
  - Examples: financial records, GAP audit records, hazard analysis, SOPs and associated monitoring documentation, etc.
- These records must:
  - Be accurate and legible
  - Be retained at the facility for at least two years after the date they were prepared
  - Records >6 months old can be stored offsite (must be retrievable in 24 hours)

### RECORDS NEEDED TO SHOW YOUR BUSINESS IS AN ELIGIBLE QUALIFIED FACILITY

- Records to support the attestations you make on Form FDA 3942a
- Records that you use for your calculations of annual sales
- Records of the actual calculations that you make
  - e.g., calculations of inflation-adjusted annual sales plus market value and the three-year average of inflation-adjusted annual sales plus market value

**Section 6 – STATUS CHANGE (if applicable)**

Human food facilities that have changed status from a "qualified facility" to "not a qualified facility" must notify FDA of that change in status by July 31 of the applicable calendar year. Check the box below to indicate a status change.

The above-named facility is no longer a "qualified facility" as defined in 21 CFR 117.3 based on the annual determination.

Signature \_\_\_\_\_ Date \_\_\_\_\_

Printed Name and Title: \_\_\_\_\_

Please check one option below that best describes your relationship to the facility.

Owner  Operator  Agent in Charge

Please provide your contact information below if it differs from the facility information provided in Section 1.

Contact Address \_\_\_\_\_

Address 1 (street address, P.O. box, etc.) \_\_\_\_\_

### BUSINESS GROWTH > \$1 MILLION

- Your food business is very successful – great!
- What happens when you exceed sales of \$1 million/year – how does that change your regulatory requirements regarding food safety?

### MONITORING AND VERIFICATION OF CRITICAL FOOD SAFETY SYSTEMS

- Consider product and process-specific hazards
  - Pathogens like *E. coli*, *Salmonella*, and *Listeria*
  - Allergens
  - Depending on the product (i.e. acidified foods) you may already have additional record keeping requirements
- Determine what activities you use to control these hazards
  - Cook step, refrigeration, allergen labeling, etc.
- Implement simple record keeping practices to document control over these hazards at established time intervals
  - Record time/temperature information, check every batch of product labels for allergen declaration statements

## MAKE SHEETS FOR TRACEABILITY BY BATCHES

- Records can be prepared by activity (e.g. cooler monitoring log) or by batch (e.g. make sheets)
- Make sheets allow small processors to record all batch-specific information on one form
  - Time/temperature for processing
  - pH
  - Type of label used and that the allergen statement was present
  - Visual inspection of cleanliness following sanitation
  - Visual check on employees following GMPs
  - Lot numbers for ingredients
  - Batch numbers of finished product

## ADDITIONAL RESOURCES



- Abby Snyder – Cornell University, collaborating with Londa Nwadike MU and K-State to help small food businesses achieve compliance with FSMA through USDA supported programming.

