

FOOD ENTREPRENEURSHIP IN THE AGE OF FSMA

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TODAY'S AUDIENCE ?

- **Geography**
 - Town with its own Health Dept?
 - Inspected by City, State, USDA, FDA?
- **Scope of operations**
 - Not yet operating
 - In-house production
 - Outsourcing production
- **Health Dept Professionals?**



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AGENDA

- The Basics of Food Oversight
- Food Reg's & Business Strategy
- Production Facility
- Food Safety & FSMA



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THE BASICS OF FOOD OVERSIGHT

“describe food, process and intended distribution”

- What, where, who
- Licensing & Jurisdictions
- Codes



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WHAT - WHERE - WHO



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WHAT - WHERE - WHO



At home

**Shared
Kitchen**

Pie Shop

Commissary

Co-packer



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WHAT - WHERE - WHO



At home	Shared Kitchen	Pie Shop	Commissary	Co-packer
Farmer's Market Patrons	Retail Online local coffee shops	Retail Online in-store local markets	Wholesale Grocery Restaurant Food service	Wholesale Grocery Restaurant Food Service



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WHAT - WHERE - WHO



At home	Shared Kitchen	Pie Shop	Commissary	Co-packer
Farmer's Market Patrons	Retail Online local coffee shops	Retail Online in-store local markets	<u>Wholesale</u> In-state Grocery Restaurant Food service	<u>Wholesale</u> Across USA Grocery Restaurant Food Service
Local & State Health Dept	Local & State Health Dept	Local Health Dept	State	Co-packer oversight



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THE BASICS OF FOOD OVERSIGHT CODES, RULES & REG'S

- **Federal – FDA & USDA**
 - Write federal food code regulations
 - Adopted by State & Local Health Depts
 - Science-based
- **State & Local**
 - Must adopt FDA at minimum
 - Supplements with add'l reg's



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THE BASICS OF FOOD OVERSIGHT CODES, RULES & REG'S

- **State of Illinois**
 - Adopted FDA 2013 code last June
 - Enacted Safe Food Handler Law 2014-2016
- **City of Chicago**
 - Adopting FDA 2013 fall 2018
 - Food handler law same as State of Illinois



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THE BASICS OF FOOD OVERSIGHT

- Questions?



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FOOD REG'S & BUSINESS STRATEGY

- **Licensure = strategic decisions**
 - How, when and where you apply
- **Look thru lens of long-term business goals**



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WHAT - WHERE - WHO



Salami	Salami	Salami
Italian Restaurant	Food Wholesaler On-site cash & carry	Salami shop
1. In-house sales only	1. Retail 2. Wholesale in-state 3. Regional Distributor	1. Wholesale & retail launch 2. Intend nat'l dist



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WHAT - WHERE - WHO



Salami	Salami	Salami
Italian Restaurant	Wholesaler On-site cash & carry	Salami shop
1. In-house sales only	1. Retail 2. Wholesale in-state 3. Regional Distributor	1. Wholesale & retail launch 2. Intend nat'l dist
Federal food safety reg's apply		
Local License & Inspections	1. Local License 2. State License 3. USDA	1. USDA



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WHAT - WHERE - WHO



Salami	Ice Cream	Salad Dressing
Italian Restaurant	Wholesaler On-site cash & carry	Salami shop
1. In-house sales only	1. Retail 2. Wholesale in-state 3. Regional Distributor	1. Wholesale & retail launch 2. Intend nat'l dist
Federal food safety reg's apply	→	
Local License & Inspections	1. State Dairy License 2. Local License 3. FDA	1. State & Local 2. FDA



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FOOD REG'S & BUSINESS STRATEGY

- Licensure is a requirement
- How, when and where you apply may not be
 - Timing, sequence important
 - Overlap of applications can be tricky
- May be more than one option
- Look thru lens of long-term business goals



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FOOD REG'S & BUSINESS STRATEGY

- Questions?



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PRODUCTION FACILITY

- Home
- Shared Kitchen
- Your own place
- Co-manufacturer



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WHAT - WHERE - WHO



At home	Shared Kitchen	Your own place	Co-packer
Cheapest	Commercial facility	Lease or Own	Investment
Farmer's Mkt only	Limits of time, space, equipment	Not shared	Producer assumes food safety liability, label approval, recipe scale
\$36K max sales	Significantly reduces barrier to entry	Bigger financial risk	
Allows gov't to enter your home	Operator manages building	You must maintain your facility	Not all or nothing; can outsource a portion of process



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FACILITY CONSIDERATIONS

- **Shared Kitchen**
 - Location, location, location
 - Quality of operator
- **Your own place**
 - Existing utility services
 - Minimal design-retrofits
 - \$300-\$325 square foot construction



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FACILITY CONSIDERATIONS

- **Co-manufacturer**
 - Ability to scale recipes
 - Critical skill for product consistency
 - May only outsource a portion of process
 - Assembly, packing, label
 - Grinding/stuffing, return for ferment/dry
 - Huge need for small-batch co-packers
 - Significant financial commitment
 - Secure experts and counsel to assist



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PRODUCTION FACILITY

- Questions?



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FOOD SAFETY & FSMA

- Historically, food regulation was reactive
- HACCP – food specific prevention measures
- FSMA shifts entire system to prevention

***Regardless of what the law requires, FSMA
is forcing sea changes in the marketplace***



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TOP FOOD BORNE DISEASES

<u>Pathogen</u>	<u>Illness</u>	<u>Hospitalization</u>	<u>Death</u>
Norovirus	5,461,731	14,663	149
Salmonella, nontyphoidal	1,027,561	19,336	378
Clostridium perfringens	965,958	438	26
Campylobacter spp.	845,024	8,463	76
Staphylococcus aureus	241,148	1,064	6
E. Coli (STEC)	63,153	2,138	20
Listeria Monocytogenes	1,591	1,455	255



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Source: CDC

ORIGIN OF HACCP

- Prevent food borne illness in space
- NASA & Pillsbury



HACCP

HAZARD ANALYSIS CRITICAL CONTROL POINTS

A systematic approach to the identification, evaluation and control of food safety hazards.



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HACCP IS A SYSTEM



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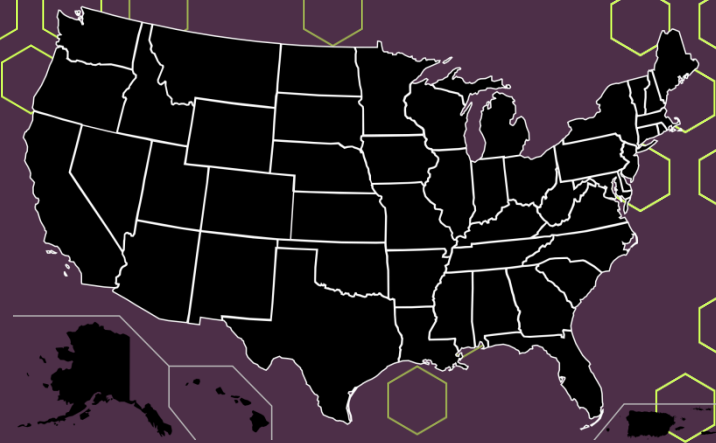
HACCP ADOPTION

1989	HACCP recommendation
1995	<u>FDA Seafood HACCP</u>
1996	USDA/FSIS Meat & Poultry HACCP
1997	<u>Revised HACCP Guidance</u>
2001	FDA Juice HACCP
2003	<u>FSIS Listeria Rule</u>
2014	FDA Low-Acid & Acidified Canned Foods
2015	FDA – FSMA Rules for Preventive Controls



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HACCP USA MANDATORY FOR:



- Fish and Fishery (Seafood) Products 21 CFR 123
- Meat and Poultry Products 9 CFR 417
- Juice Products 21 CFR 120
- FDA local variances 3-502.11 -12
 - Vacuum packaging & sous vide
 - Curing food
 - Smoking food to preserve it
- Remember, dictate State & Local Health Reg's



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HACCP KEY POINTS

- When required, HACCP plans must be submitted and approved by regulatory authority
- HACCP training required
- Operator must have documents to prove food safety compliance
- Practices must match what's on paper



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FOOD SAFETY MODERNIZATION ACT

- Passed by Congress 2011
- Took effect fall 2016
- Requires *preventive* controls for all human and animal food



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FSMA COMPLIANCE DATES

- 9/18/16 Gen'l Compliance (Big Food)
- 9/18/17 Small Businesses (>500 employees)
- 9/18/18 Very Small Businesses (>\$3MM)

Big Food compliance is forcing adaptation through the supply chain



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APPLICABLE CODES

- Illinois – FDA 2013
- Chicago – FDA 2009
- Local small food businesses will feel FSMA sooner than law requires



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FSMA - HACCP ON STERIODS

- All food requires Preventive Controls
 - HACCP becomes HAP-C
- Allergens controls
- Farms
- Supply chain verification
- Food Safety Audits
- Traceability & Recall
- Training requirements



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ALLERGEN PREVENTIVE CONTROLS

- **MUST** be indicated on label as an ingredient
- “may contain” or “produced in a facility” – no more
- **70%+** of USA food recalls due to undeclared allergens

Milk	Wheat
Eggs	Soy
Fin Fish	Peanuts
Shellfish	Tree Nuts



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FARMS

- FSMA defines a farm
- Requires GAP's on farms
- Customers may require GAP 3rd party certification
- Final Produce Rule



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SUPPLY CHAIN VERIFICATION

- Food companies bear responsibility for vendors' products
- Preventive controls required in supply chain if not controlled at production site



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TRACEABILITY & RECALL

3RD PARTY AUDITS

- All parties in supply chain must be able to trace one step forward and one step back
- Mock recall is required component of passing a 3rd party audit
 - Large companies required to comply are requiring vendors to produce an audit



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TRENDS

- Food reg's are only getting tougher—squeezing small players out
- Document reviews/req's heavy duty
- Training in HACCP and PCQI a must
- Technology adoption forced
- FSMA will continue to creep into state and local jurisdictions



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NOT FOR FAINT OF HEART

- **Have clear objectives**
 - Personally & professionally
 - Set limits on time, money, all resources
- **Food Safety Manager Certification**
- **Insurance**
- **Product R&D**
 - Farmer's markets great route
 - Welcome the critics
- **Facility selection**
- **Logos, website, branding-- later**



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FOOD SAFETY & FSMA

- Questions?



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THANK YOU!

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