First Nations Knowledge Webinar Series
Announcements

• Questions:
  – Phone/Mic. Raise your hand we will unmute
  – Listen: Type in and we will read

• Evaluation: survey when webinar ends and in an email

• Recording and attachments can be downloaded from www.firstnations.org/fnk
Next Webinar

- Farm-to-School Best Practices For Native Communities
- May 23^{th} 12 (MT)
Food Safety Sovereignty
Food Safety Challenge for Small Businesses

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Issues for Today

• What laws could affect tribal food businesses?
• What new legal requirements are coming?
• How should tribes and tribal businesses respond?
Poll Question 1

• What do you think the greatest risk is to food safety?

1. Bacteria and viruses
2. Chemicals (pesticides, additives, environmental toxins)
3. Allergens
4. Terrorists or disgruntled employees who might contaminate our food
5. Economic fraud that makes people sick
What Are We Worried About?

• Safety of fresh and minimally processed foods because of recent microbial food borne illness outbreaks

• A small mistake can have massive effect

• No ‘kill’ step for microbes

  Recent outbreaks: brined fish, lettuce, minced tuna, melon, sprouts, spinach, Serrano peppers, peanut butter, almonds
Why Is There An Emphasis On Food Safety Now?

• Outbreaks and contamination incidents are global and wide reaching

• Microbial and chemical contamination risks—intentional and unintentional causes
  ▪ Failure of companies or governments to remove suspected or known contaminated foods from the market
Businesses Must Be Aware of Hazards

• Must address both accidental *unintentional* hazards and *intentional* contamination

• Unintentional Hazards:
  ▪ Biological
  ▪ Chemical
  ▪ Physical
Intentional Hazards – Deliberate Contamination

Intentional hazards can realistically be controlled through:

• supplier guarantees and audits (to some extent),
• traceability (and market withdrawal),
• monitoring of employees and others for suspicious activities
Traceability

- Put a traceability feature and generate receipts reflecting sales recommended (fishers)
  - Commercial buyers will require this
  - Restaurants are starting to demand traceability
  - Receipts can help future sales since you have contact information for your customers
Moving to the Next Level – Putting Traceability Tags on Fish
The Best Kind of Traceability Tags

Wester Ross Salmon
Hand Reared in a Rugged Land

Hand Reared in Scotland
Every Wester Ross salmon gets a unique, sequential number. Cut Tag in Half for Fillet.

000001
Poll Question 2

What is the best way to make food safe?

1. Have inspectors at food processing plants all the time
2. Businesses (even small ones) and restaurants should have food safety plans and trained employees
3. Consumers should store and cook their food properly
Goal of Food Safety Laws: No Adulterated Food

• *Reasonable probability* that the use of or exposure to an article of food, and any other food that is *likely to be affected* in a similar manner, will cause *serious adverse health consequences or death* to humans or animals
Moving to the Next Level for Tribal Businesses

• Value of tribal businesses to the community
• Distributors, secondary processors have to meet new food safety requirements and are passing these requirements back to their suppliers
• Restaurants want authentic, traceable food
• Consumers want to know that their food is safe
Poll Question 3

• What business are you in?
(You can pick more than 1 answer)
1. Farmer or fisher
2. Seller - direct to the public
3. Processor
4. Sell or distribute to other processors
5. Sell to retail stores or restaurants
Three Types of Food Businesses

• Food service establishments
• Food processors
• Exempt or partially exempt food sellers
Food Service Establishment

A place, location, operation, site or facility where food is manufactured, prepared, processed, packaged, dispersed, distributed, sold, served or offered to the consumer regardless of whether or not compensation for food occurs

Regulated by state, licensed/inspected by county/municipality
Food Safety Regulations That Affect Your Business

• Food service -
  ▪ State recognized “food handlers card”
  ▪ Good sanitation, personal hygiene and temperature control at sales location
  ▪ Records and written sanitation plan is recommended
Food Service Workers Need Training

• “Health cards” or “food handlers” card issued by state or county needed
• Some tribal sanitarians provide this training
Required Training for Food Service Workers

• In Washington (and most other states) at least 4 hours of “food safety training” is required on:
  ▪ proper cooking
  ▪ hot-holding
  ▪ cold-holding and cooling of potentially hazardous food
  ▪ preventing cross contamination
  ▪ sanitation
  ▪ HACCP
  ▪ proper hand washing techniques
  ▪ Personal hygiene
Food Safety Regulations That Affect Food Business

• Food processor or distributor –
  ▪ Registration with FDA (for produce, processed foods except meat, fish)
  ▪ Comply with FDA mandated:
    • good manufacturing practices (GMPs),
    • sanitation program requirements,
    • food protection program based on HACCP
    • traceability
  ▪ Business is subject to inspections, administrative detention, and recalls by FDA
Farmer’s Markets Sales May Be Exempt

• Farm direct marketer (as in Oregon) for those that raise their own products and sell them directly to a consumer;

• There is confusion over who is exempt (produce sellers) and who is not (fishers?)

• Depends on the state you are doing business in

• State laws are not clear
Farmer’s Markets Sales May Not Be Exempt

• *Intermittent food markets* ((< 3 days at a single location) (in Idaho) who sell *potentially hazardous foods* require a state license and are subject to inspection

• Produce safety rules under FSMA may require people at farmer’s markets to do more (but we are not sure yet)
Most Important FSMA Requirements for Food Processors

• **New** - Mandatory HACCP-based Food Protection plan and associated records

• **New** - Records access - expanded beyond suspect foods to other that may be similarly affected – “reasonable belief”

• Administrative detention

• Registration

• Traceability

• Prior notice for imports

• **New** - Importer verification programs
New FSMA Requirements - Traceability

• Tracking – most significant feature in food trade

• Focus on how this can be used in your marketing program
Poll Question 4

Will FSMA affect:

1. Small businesses more
2. Big businesses more
Impact of FSMA on Businesses and Consumers

- Key features of Food Safety Modernization Act will cost a lot of money – 2014 over $259,000,000
- FDA lacks resources including enough qualified staff to handle all tasks
- Regulations and guidance are late
- Agency is shifting to a fee-driven model - FDA is proposing fees for registration possibly in violation of treaty rights
- Non-uniform domestic enforcement will force food businesses off shore
- SO we will have MORE imported food!!
FSMA - One Size Fits All Approach

• Does not “work” for small food producers – most tribal food businesses are small

• Will affect distributors and transporters
  ▪ Supply chain complexity
  ▪ Traceability
  ▪ Global nature of food business
Problems FSMA Causes for Small Business

• Industry consolidation from higher costs
• Loss of small producers of “high risk foods” - fresh produce, aquatic foods

• SOLUTION: Work with others to develop generic plans, records, audit programs and test protocols that could reduce overall compliance costs for everybody
Complying with FSMA

• FDA will require a Food Protection Plan with:
  ▪ suitable preventive controls,
  ▪ monitoring program,
  ▪ and records
  to guard food against intentional AND unintentional contamination

Focus on high risk foods and processes

SUGGESTION: if you don’t have a plan – start on one now!
How Will This Law Affect Tribal Businesses?

• Non-traditional reach of statute – how deep will FSMA go into a company’s operation?
  • ANSWER: Not sure. For tribal businesses, little if any consultation with tribes occurred

• What will regulations look like:
  • ANSWER: Nobody knows, major rules are just coming out, FDA is way behind schedule
  • Must be proactive
Recent Survey – Will a New Federal Law (FSMA) Strengthen Food Safety?

• Vastly – 25%
• Moderately – 36%
• Barely – 37%
Will Our Current Food Safety Programs Be Recognized?

- ANSWER: To some extent - Compliance with ‘Seafood HACCP’ for fishers should cover most issues; but must address new hazards of intentional contamination, radiological hazards, decomposition, allergens

- ANSWER: Produce and other foods will require new and more complicated food protection plans
Poll Question 5

What makes food safer?

1. Testing the food and ingredients for chemicals and bacteria
2. Controlling processes for making the food
3. Both
HACCP is “Process Control” but FSMA Will Require More Testing and Audits

- More testing and certifications will increase costs of food production and storage
- Outsourced testing services will increase since labs must be “accredited” to do each specific test
  - In-house lab results will not be accepted if lab is not accredited
  - SOLUTION: Determine how much testing you will need and the most cost effective way to do it.
  - Consider establishing an in-house accredited lab for critical or common tests.
Costs of More Tests and Audits

- Direct costs of verification and audit programs are high
  - Current ~$100,000 per year for medium sized processing facility with refrigerated/frozen storage
  - Cost likely to increase for domestic producers
  - Costs will increase for foreign producers exporting to USA but compliance monitoring will be incomplete giving foreign producers a competitive advantage
  - Third party audits will be accepted for imported foods
  - SUGGESTION: Plan for these additional costs
FDA’s Plan of Attack - Targeting Non-Compliant Firms

• Statute is vague

• Excessive discretion provided to federal officials who have their own career ambitions

• Who may act haphazardly and may not be well trained

• High proposed fees provide incentive to “go after” companies to get more money

Tribal food processors face this risk
Targeting Non-Compliant Firms

- FDA has a lot more authority now
  - SUGGESTION: have a qualified attorney review food protection plan. Develop crisis management programs, recall programs and the related press, prepare for inspections
- FDA will publicize food safety issues
- FDA will financially penalize firms for food safety failures
- SUGGESTION: have a recall plan and a designated person to communicate with media
Specific Requirements of FSMA

- Inspections of records
- Registration of food facilities
- Hazard analysis and risk-based preventive controls
- Performance standards – fresh produce, high risk foods like seafoods, dairy
- Protection against intentional adulteration
- Sanitary transportation of food
- Food allergy and anaphylaxis management
- New dietary ingredients
- Bars to port shopping
More Specific Requirements for FSMA

• Targeted inspections
• Accreditation of food analysis laboratories
• Enhancing traceability and recordkeeping
• Disease surveillance
• Mandatory recall authority
• Administrative detention of food
• Decontamination and disposal standards and plans
• Improving the reportable food registry
Inspections

• FDA can inspect anyone (excluding farms and restaurants that do not sell packaged food to public) that manufactures, processes, packs, distributes, receives, holds, or imports food

• Get ready for an inspection – for high risk foods within the next couple years
Rate of Inspection

• High risk foods (3 years)
  ▪ 22,325 firms in USA
  ▪ In 2012, FDA inspected 7,400 high risk and 8,600 low risk firms
  ▪ Inspecting more in 2013
High Risk Foods

- Known safety risk
- Based on broad industry level of risk
- Class 1 recall in past five years
- Compliance risk of particular facility

Recommendation: Categorization will not remain static – so companies will need follow emerging food safety risks and recalls
Increase in Warning Letters Issued

• Seafood:
  ▪ increased 42% from 2009 to 2010
  ▪ increased another 43% from 2010 to 2011

• Targeted domestic producers for HACCP (58 %) and GMP (37%) violations; some canned food (2%) and misbranding (4%)

With new fee structure, FDA has a financial incentive to issue more warning letters since these will lead to reinspections that generate fees
Trends from Warning Letters

• Most common seafood HACCP violations:
  ▪ inadequate temperature control
  ▪ lack of HACCP planning
  ▪ lack of product specifications/verification (for importers)

• More *Listeria* spp. testing

• Common GMP issues are important and not controlled

• HACCP documentation is critical and tends to be deficient,

• There will be a focus on environmental microbiological testing
Odd Features of These Warning Letters

• FDA finding that the ‘affirmative step’ of obtaining foreign suppliers HACCP plan is inadequate because a foreign supplier’s HACCP plan was flawed

• Requirement for environmental controls on Chesapeake Bay

• Fishing area for crab challenged (but not in association with a closure)

• Nutritional claims about “low fat” fish and reducing body weight

Warning letters may be used to expand FDA authority. Indications are that there are a lot of inexperienced inspectors out in the field!
Records Inspection

• You must permit FDA (with written notice) at reasonable to:
  ▪ View and copy all records relating to a food OR records for a *similarly affected* product
  ▪ FDA wants records to determine if the food poses a reasonable probability that use of it or exposure to it will cause serious adverse health consequences or death to humans or animals
  ▪ **RECOMMENDATION:** Records must be complete, accessible, BUT with commercially sensitive information and intellectual property redacted. Get legal advise.
Administrative Detention of Food is Easier to Do Now

• Old standard of “credible evidence or information” is replaced by “reason to believe”

• Old standard of “presents a threat of serious adverse health consequences or death to humans or animals” is replaced by “is adulterated or misbranded”
Mandatory Recall Authority

• “Reasonable probability” food is adulterated or misbranded and would cause “serious adverse health consequences or death”

• Public is notified
FSMA – Strategy to Improve Safety of Imported Food

- HACCP compliant foreign producers
- Inspection of foreign food facilities
- FDA foreign offices
- Capacity of foreign governments
- Accreditation of third-party auditors
- Foreign supplier verification program
- Voluntary qualified importer program
- Import certifications for high risk food
- Prior notice of imported food shipments
- Controlling smuggled food
New FSMA Requirements – HACCP Plan and Records

• HACCP based Food Protection Plans

• Recommendation: Obtain a copy of and review supplier HACCP plan, get their records.

• Records – FDA now has access to records beyond those related to a specific suspect food
  ▪ Agency “reasonably believes” other products are likely to be similarly affected
Areas of Greatest Impact to Food Industry

- A large number of new requirements placed on relatively low risk sectors and more requirements on high risk sectors
- Everybody must have validated preventive controls
- Traceability will have greatest impact (and is area FDA is seeking assistance from industry)
- New recordkeeping, enhanced records access
- Enhanced prior notice - must notify FDA if *any* country *anywhere* has refused entry
- New import clearance programs
Summary – Impact of FSMA

• FSMA HACCP requirement should increase overall food safety
• Some small business exemptions, but not all details are out yet
• Provisions are redundant with other laws - new requirements and records will lead to higher cost
• Pressure for additional product testing, environmental monitoring, and 3rd party audits
• Regulations and guidance are still to be drafted
• Full Congressional funding is questionable
• FSMA are considered by other countries to create non-tariff trade barriers
Provide Input to FDA

• FDA recognizes that it lacks the capability to develop regulations and guidance for FSMA without industry input

SUGGESTION: Provide direct input to Agency for more sensible regulatory framework and requirements
What works

• Speaking with a unified voice
• Coordinate across a trade sector – seafood HACCP (1995)
  ▪ generic plans and records
  ▪ continuous, on-going, cheap training by a wide range of qualified individuals
• Focus on food safety as part of a good market strategy
Thank you – any questions?