

General Food Safety Liability and Introduction to Legal Issues in Marketing

Janie Simms Hipp, JD, LLM (Chickasaw)
Director, Indigenous Food and Agriculture Initiative



UNIVERSITY OF
ARKANSAS

School of Law

Indigenous Food and Agriculture Initiative

Definition

- In Indian Country:
 - Tribes are deeply involved in food
 - \$3b annual income across Indian Country (approx. 1/2 livestock; 1/2 all other)
 - Business of food and agriculture done through
 - Tribal governments
 - Tribal business arms
 - Tribal business ventures
 - Tribal individual producers
 - Tribal nonprofits and community based organizations
 - And all of the above

Food Safety Liability

Food safety is divided into categories called “hazards”

Biological hazards

- Bacteria, molds, naturally occurring toxins

Chemical hazards

- Petroleum, herbicides, pesticides, heavy metals

Physical hazards

- Glass, rocks, wood splinters, bugs

When we talk about food safety we often talk also about “micro-organisms”

- Bacteria, parasites, viruses, yeasts, and molds
- Usually too small to be seen by the naked eye
- Important to actually see these things in a lab so you can see what we are talking about

Before We Begin: Imagine

Fact situation

- 50 producers working with the Tribe on food and agriculture within the jurisdiction of Tribe of Food
- Food company (functions like a food hub also) sits on border of the State of Thrones
- Half of the producers are in State of Thrones; half are in Tribe of Food
- In business for five years
- Profitable for individual producers and for food company of the tribe
- Bottom line for all producers and the food company is increasing annual profit and sustainability in order to improve economic situation and access to foods
- Didn't incorporate - loose coordination of producers loosely connected with the company



More Imagining: Bad Situation

Major listeria outbreak in the State of Thrones and in the Tribe of Food

- Five dead
- Fifty hospitalized
- Ten in ICU for a month
- Product is traced to 2 of the 50 farms in the food region
 - One farm is in Thrones (state) jurisdiction; one is in Food (tribal) jurisdiction

Those 2 farms recently were taken over

- Bought out
- One farm bought out by a corporate investor that is connected with investment company – intention is to stop farming
- One farm bought out by the family of the owner
- The investor-owner farm has elaborate documents shielding it from liability
- The family owned farm hasn't incorporated yet under the new owners and the previous owners weren't incorporated

Food was labeled and marketed as “natural”, “non-GMO”, “healthier for you”, and “the best for you and your baby”.



Listeria bacteria - - the food hazard

Listeria bacteria

- Human infections follow consumption of contaminated food
- When listeria gets into a food factory or food handling location, can live there for years
- Can be found in a variety of foods
- Uncooked meats and vegetables
- Unpasteurized (raw) milk and cheeses and other foods made from unpasteurized milk
- Cooked or processed foods, including certain soft cheeses, processed or ready-to-eat meats, and smoked seafood

Killed by cooking and pasteurization

Can grow and multiply in some foods in the refrigerator



Impact of listeria

Case-fatality rate of about 20%

- Clinical manifestations are sepsis and meningitis and meningitis complicated by encephalitis
- Can be found in soil which can lead to vegetable contamination
- Animals can be carriers of listeria
- Can be found in fruits such as cantaloupes, apples
- Pasteurization and sufficient cooking kill listeria
- Best way to deal with listeria is to avoid it altogether



More Imagining

When the 2 farms were taken over, there was no new insurance acquired by the time of the food safety problem

10 of the other 50 farms in the region also let their insurance lapse

All 50 farms had decided that they were exempt under the new FSMA rules, but no one had a written confirmation of the exemption from any regulatory agency

Half had a HACCP plan, half did not

- Hazard Analysis Critical Control Point (HACCP)

Only a few had GAP plan or audited operation

- Good Agricultural Practices (GAP)
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Baby Jay

Baby Jay's mom - who survives him - hires a lawyer

Baby Jay spent weeks in ICU on life support - Ultimately passes

What happens next?

- Baby Jay's Mom hires a law firm
 - The lawyers for Baby Jay's mom file a lawsuit against the food company and all 50 of its affiliated farms
 - The food litigation actually happens quicker than the conclusion of the state/federal/local investigation and trace-back
 - The administrative agencies are contemplating further action, but no "recall" was able to happen - - by the time the possible sources were identified, the food from all the farms was co-mingled to such a degree that identity of the culprit farm was murky
- 

In the course of the litigation

Trace back from the consumer to the business and to the farms

Investigation of the “legal status” of the farms and the business itself

- What sort of business was it?
- Was it a sole proprietor?
- Was it a corporate structure of the food company and individual farms?
- Where are the records?
- Are there records?
- What are the agreements between the parties?
- Who is in control of the company’s day-to-day operation?
- Does it have a board of advisors?
- Who is in control of the multiple farms’ day-to-day operations?
- Have the food companies complied with food safety, marketing and labeling requirements?

The lawyer for Jay’s Mom is LOOKING FOR A DEEP POCKET TO COMPENSATE HER FOR THE LOSS OF HER BABY



Possible administrative response

Could involve intense investigations

Could imply the food company and its entire supply chain in the investigations

Could involve publicity and warnings to the public

Could involve civil penalties, administrative fines

Could also now involve criminal prosecution

Could involve recalls and voluntary removal of product from anywhere it's gone in the food chain, up to and include consumers refrigerators

Could also involve civil lawsuits



Business entity

What sort of business entity is the food hub?

What sort of business entity are the individual farms participating in the hub?

Choices for all

- C Corp, S Corp, LLC, L3C, Joint Partnership, Cooperative, something else?

Indian Country choices involve other options as well



Business entity

Business entity selection is normally driven first and foremost by issues related to taxation of the entity and the overarching business plan of not only the business itself but the farmers involved with the business

Business entity selection should be done at the outset of launch of the business

Does a business entity protect you from liability?

- Hmmmmm. Not really
- Courts have been more and more willing to impose liability on the business entity principals, business owners, those making decisions, etc.

Does the business entity protect you from lawsuit?

- NO, Never!
- 

Types

Sole proprietor

- Unincorporated person or family
- Report personal and business income and taxed as individual
 - YOU NEED SEPARATE ADVICE CONCERNING YOUR TAX EXPOSURE IF YOU ONLY PRODUCE AND SELL WITHIN TRIBAL JURISDICTION

Partnership

- Partners are not employees
- 2+ persons – each contributes
- Does not pay income tax as an entity
- Passes through profit/loss to individual partners

Corporation

- Same deductions as individual sole proprietor
 - Profit taxed to corporation
 - Profit taxed to shareholders of corporation when they receive dividends
- 

Types

S-Corporation

- Election when create
- Pass income/loss/deduction to shareholders
- Profit/loss reported by shareholders

LLC (limited liability corporation)

- Allowed by state statute (can be different state-to-state)
- Taxed as separate entity from owners
- Can be single member or multiple
- Tax treatment depends on how LLC elects to be treated

Cooperative

- Profits distributed to members
- Operates as a corporation
- Income to member treated as earned income

Nonprofit corporation

- IRS grants status
 - Taxation unique to nonprofits
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Types – Indian Country

L3C

- Low-profit limited liability company
- Intended to bridge the gap between non-profit and for-profit structures
- **Facilitates investments in socially beneficial, for-profit ventures**
- **Relies on IRS rules for program-related investments by nonprofit and private foundations**
- Combines the legal and tax flexibility of a traditional LLC, the social benefits of a nonprofit organization, and the branding and market positioning advantages of a social enterprise
- Articles of incorporation required to follow federal tax standards for program-related investment

All of the above plus

- Section 7 corporations – sanctioned by the Secretary of the Interior
 - Tribal nonprofit – under tribal law
 - Tribal corporation – under tribal law
- 

Other Considerations

Other considerations

- Workers comp
- Unemployment comp
- Sales, property and related state and local taxes (different in Indian Country)
- Who applies for permits
- Who responsible for environmental, health, safety, etc.
- Who gets paid and how
- Board responsibilities, etc.

Business entity

What attributes of a business entity are meaningful in this fact situation

What is important?

- Shielding your personal assets from lawsuits, if possible?
- Shielding your personal assets from claims of your creditors of the business, if possible?
- Discipline necessary to maintain the entity? Does it exist? Can it be acquired in the form of a business manager or advisor?
- Record keeping is the touchstone for the business, regardless of its entity selection

Sole proprietors are the most “exposed” type of business entity

And, even if you are an “entity” the courts can still pierce your entity selection and attach liability to you personally



Possible Food Safety Liability Scenarios

In our fact situation...

Will the food company protect the farmers from a lawsuit? NO

Will the food company be sued? YES

Will the farmers be sued? Likely

Will all fifty farmers be sued? Maybe

Why?

Because the lawyer for Baby Jay's Mom wants to trace the food to all conceivable sources and attach liability to each source

The burden will be on the company and its affiliated entities (farms) to extricate themselves from the lawsuit



So what next?

Each farmer or food company must hire a lawyer

Each lawyer will try to extricate his client from the lawsuit by saying the food can't be traced to his client's farm

How long will this go on?

- A LONG TIME!

How much \$\$ will be involved?

- Likely, a lot.

Consider developing a corporate business entity structure for your food company or farming/ranching business. But that's only the beginning of examining and dealing with your risk.



What kind of liability

Food Safety Liability

Strict Liability

Food liability is product liability

Food is a "good" under the Uniform Commercial Code

Goods have warranties that attach to them when they move through commerce

The manufacturer or source of food is liable for the harm it causes in the stream of commerce



Investigations and Discovery

When food harm is caused, an investigation will be undertaken by the state, local and/or federal authorities

If a lawsuit is filed, discovery (which is a form of investigating the facts) ensues

The purpose of investigations or discovery is to find the source of the problem

Chain of custody/evidence

Reminder: We live in a “CSI-World” of food!



The Source

The source of food borne illnesses normally result from:

Unsanitary conditions in processing, storage, handling, harvesting, production, transportation etc.....the food chain

Contamination of the food source

Unclean food handling at any step

Your standards may not be your farmer neighbor or food company neighbor standards



Liability

In the US, normally those placing food into commerce are held to standards of strict liability

Strict liability doesn't require "intent" to cause harm

You put it in commerce and it caused harm, therefore you are strictly liable

Those harmed don't even have to prove the exact cause of the problem....only that there was a problem of some type that caused harm



Warranties

Even if there isn't strict liability, it's still easy to hold someone liable for violation of warranties

Types of warranties

Express (written or said)

Implied



Warranties

Express warranties

The seller (up the chain) stated either in writing or orally as part of the sales transaction that the goods were of a certain type, quantity, quality....and were free from defects

Read the contracts!

Express warranties can also happen when writings about the food product change hands between the parties

- Ex: the product has certain attributes or meets a certain level of quality; warranties/language on the packaging

Express warranties can also occur when there is evidence that oral statements occurred



Warranties

Implied warranties

The courts imply certain warranties, even if they are not stated orally or in writing

These implied warranties are:

Merchantability - - the product is guaranteed to work as claimed

- Conform to the standards of the trade
- Fit for the purposes such goods are ordinarily used for
- Uniform as to quality and quantity within certain tolerances for difference
- Packaged and labeled per the contract for sale
- Meet the specifications on the package labels
- Fitness for particular purpose (eating)

Fitness for purposes - - If it was not fit to eat, what is the source of its unfitness?

Did the business(es) take reasonable care to ensure fitness and safety and merchantability?



Implied Warranties

Examples:

- Yogurt will not contain pieces of shredded plastic
- Apple pieces bags will not contain pieces of animal parts
- Recent Example:
 - Rice Krispies in Europe - - intact small bat found in the box of cereal

Implied warranties don't normally cover ordinary wear and tear, improper maintenance, failure to follow instructions

Don't cover every possible failure of the product

Generally there is no specific duration of the warranty

States will differ as to the statute of limitations on implied warranties



Disclaiming Implied Warranties

Under the UCC, sellers of products can exclude or modify implied warranties

But, in order to do so, the exclusion of the warranty has to be provided in a record (printed document, such as a sales document)

Must be conspicuous

UCC provides specific language

- Warranty of merchantability: “The seller undertakes no responsibility for the quality of the goods except as otherwise provided in this contract.”
- Warranty of fitness for particular purpose: “The seller assumes no responsibility that the goods will be fit for any particular purpose for which you may be buying these goods, except as otherwise provided in the contract.”



WARNING

Not all states have adopted all sections of the UCC exactly as other sections have adopted those provisions

There ARE differences state to state

There are also differences in statute of limitations (time within which a suit must be brought) from state-to-state

Can be differences in state and local law protecting farmers and food businesses

CHECK State and local statutes and ordinances

In this fact situation, check the State of Throne and the Tribe of Food's statutes and tribal laws, for sure....and I would also check the state where delivery of the product to consumer is happening, if that is different from tribe to state



Regulations

The federal food laws that regulate foods also have standards that require that foods do not:

- Contain harmful substances
- Are unfit for human consumption
- Contain some filthy, diseased or animal substance
- Manufactured, produced in unsanitary way
- Food not protected while on business premises

And states and localities and tribes also have food laws that may impose different language into the transaction

Do your homework



WOW!

So what's a food company to do? And what's a farmer to do?

The same thing that any reasonable business person would do to take precautions and try to limit liability

Manage risk

Manage exposure to risk

Examine practices and relationships

Get and keep insurance and read your policies

Expect high levels of standards from everyone you are in business with

Their actions may imply your liability



Protection

Examine the food chain to the food company and consumer

Take steps to protect the food company and farm itself

Take steps to impose similar standards or desired standards on all members of the food chain equally

Impose standards within the supply chain and enforce those standards.

No paper tigers!

Transparency and clarity



Standards and contracts

Determine the standards at the federal, state, local level

Determine the standards at the tribal level also

Require that each relationship become the subject of a written contract

Each written contract outline the safety standards of each step in the chain

Require that each step in the chain have, obtain, maintain, and prove they have sufficient product liability and general liability insurance

Determine whether and which business entity makes sense for the hub itself



Records

Keep immaculate, thorough, and comprehensive records of each deliver, shipment, and all actions related to foods passing into and out of the company and from the farms

Why?

Easier to trace back in the event of a problem

If I'm innocent, easier to extract myself from a lawsuit

Records, records, records, records, records



Policies

Make sure cleanliness and sanitary standards are your top priority and prove it

Make sure cleanliness and sanitary standards are your hub participants top priority and make them prove it

Audit your hub participants regularly and randomly

Require written proof of insurance and written records examination at any time

Keep up with ALL changes in the laws and regulations related to food!!!!



Relationships

Seek, have, and maintain good working relationships with all regulators, health and ag departments at the federal, state and local level and tribal level

Meet with them regularly

Seek openness and manage relationships with them

TRAIN ALL EMPLOYEES

Ensure there are ongoing means to establish inter-dependent relationships and a culture of excellence at the hub and among the participants with the hub



So, is Indian Country different

Yes

General principles of prevention, relationships, reasonableness, duties, and responsibilities are the same generally

However, the legal frameworks and jurisdictions are different and require different responses



Insurance

VERY IMPORTANT TO CARRY GENERAL
AND PRODUCT LIABILITY INSURANCE
(AS WELL AS CROP INSURANCE FOR YOUR CROP)

YOU CAN'T LEAVE HOME
WITHOUT IT



UPON BEING SUED

Business Entities and Permits and Compliance with Regulations and GAP certification and HACCP plans and records do NOT shield you from being sued for food-borne illness

What all those things do is add to your ability to protect yourself should you be implied in a food borne illness outbreak

They also provide evidence of your reasonableness in actions taken in the conduct of your business

But, you can still be sued.....



Upon being sued

Make sure you hire a competent lawyer

Your food company and your operation may be at stake

Take your food safety responsibilities seriously

Keep the best records you can possibly keep

Become a business entity - - choose the one that's best for you – get advice from an attorney and accountant!!!

Your food hub and your producers are your team - - get a good lawyer and accountant on your team also.



Market Liability Concerns

Major liability concerns for food companies as they begin:

Marketing Opportunities

Market Certifications

Marketing Claims and Labels

Product Liability Risks

Regulatory Compliance

Liability for Type of Food

Isn't all about financial returns, profit and return on your investment - - it's also about what you are saying about your food, where it is being marketed, and whether you are exposing yourself to undue risk.

Analyze your risk in Marketing

Why Do We Care About Market Liability

Why do we care about these issues

- Compliance costs
- Impact on your business plan
- Minimize risks
- Increase return on your investment
- Maintain profit margins so that your business can become more solid, sustainable, and continue to grow in stability
- Be prepared for new marketing opportunities
- Staying within the law
- Minimizing risk of legal exposure
- Managing product liability
 - Food liability is strict product liability = liability without intent to harm or identification of fault

Managing Liability

Managing liability for your food product

- Prevention
 - Food safety planning
 - Verification of your safety for your buyers
 - Verification of safety for any suppliers to you
- Preparation for worst case scenario
 - Planning for recall
 - Liability in your contracts
 - Indemnification of your supply chain
 - Qualification and maintenance of insurance
 - Protecting your reputation
 - Knowing that a problem with you will spread skepticism to others in your tribe or in your food product area
 - \$ impact of damage to reputation can be more hurtful than the costs of recovering from recall or administrative investigation
 - Your reputation is worth protecting

Product Knowledge

Products

- Where are they grown
- How are they grown
- Who grows them
- How are they handled, stored

Analysis of hazards exposure

- Food safety plans, procedures, audits, inspections, records, corrective actions, complaints

Contracts with those in the supply chain

- Suppliers, buyers, contractors

Insurance policies

Why Do We Care About Marketing and Labeling

Labeling and marketing regulation

You are not free to say whatever you want about your food

If you cannot legally make a claim about your food, then find another way to talk about your food

Don't call it what it is not

Don't call it "organic" if its not

Don't call it "all natural" if its not

Who Regulates Food Marketing

Who regulates food marketing

- FDA
- USDA
- Federal Trade Commission
- Alcohol and Tobacco Tax and Trade Bureau
- State and city governments
- Consumers who say you have deceived them and sue you in class actions or individual cases
- Competitors who say you are engaging in unfair competition
- Self-regulation bodies (voluntary)
- State Attorneys General (consumer protection statutes)
- Others who sue you for what you say

Where Are Marketing Claims

Where

- Package labels
- Sell sheets
- Website
- Social media
- Trade shows
- Marketing materials
- Paid advertising

Organic and Non-GMO & Other Programs

Non-GMO

- Fastest growing third-party certification
- Whole foods - - all GMO foods in its stores must be labeled by certain date
- State labeling laws (Vermont)
- Federal legislation to address GMO labeling still being discussed in Congress

Organic - - 4 levels

- May use the seal
 - 100% organic
 - “organic” = 95% minimum
- May not use the seal
 - Made with organic ingredients = 70% minimum
 - Listing of organic ingredients

Voluntary certifications

- Must use reliable third party to verify
- Voluntary: GMO Project; Kosher; Vegan

Consumer Protection

State Laws - - Consumer Protection

- Marketing practices that involve health and safety
- Deceptive practices used to market health products
- Practices implicating food safety concerns
- Questionable health benefit or nutrition claims of food or food supplements
 - Ex: Connecticut AG in 2004 sued 2 snack food companies alleging that they falsely claimed their products could help increase energy and fight off illnesses
- Unfair and Deceptive Acts and Practices
 - Based generally on state model codes
 - Every state has laws that prohibit deceptive trade practices such as false or misleading advertisements, bait and switch, and fraudulent marketing
 - Smaller group of states have laws that prohibit unfair acts
 - A minority of states have laws that prohibit unconscionable business practices
 - Some states have targeted laws to types of practices
 - Consumers can also bring lawsuits on their own

Consumer Laws

Consumer law violations

- Overall impression is misleading
- Tendency or capacity to deceive the consumer
 - Actually being deceived isn't required
- Viewed from perspective of a “reasonable consumer”
- Laws are broadly interpreted in favor of protecting consumers
- “Unfairness” can be defined differently in different states or jurisdictions
 - Offends public policy
 - Immoral unethical, oppressive, unscrupulous
 - Causes substantial injury to consumers
 - Reprehensible conduct
 - Blatant disregard of rights of innocent purchasers

Food Marketing Law: A Fairly Recent Approach and Scrutiny

Enforcement of Food Marketing Laws (by State AG's)

1980s

- Modern day start of Food Cops - - 8 AG's - - began focusing on unsupported and misleading food labeling and health claims
 - Challenged marketing practices of food processing companies, breakfast cereal makers and fast-food restaurants

1986

- Agreements with national fast food chains requiring chains to provide nutritional and ingredient information
- Failure to disclose was a violation of deceptive and unfair trade practices and food labeling laws

FDA (health claims; Organics (USDA); Breed-specific claims (Meat Industry); etc. - - marketing claims and label claims are controlled by a variety of entities

Types of Claims Challenges: A Few Examples

Types of claims that the State AG's challenged:

- “lean meal” - - Arby's
- “real cheese” - - Cheez Whiz
- “hypoallergenic” - - Carnation infant formula
- “no cholesterol” - - Crisco
- “soup is good food” - - Campbell's
- “light” - - Sara Lee's desert
- Cholesterol reduction - - Nabisco
- “energy-releasing” B vitamins – Kellogg cereals
- “snack” and “good for you” – Frosted Flakes

Food Marketing Compliance

How to comply and plan for food marketing compliance

- Understand labeling laws and use of words to describe your product
- Do your “naming” homework
- Structure a label in accordance with FDA and USDA (meat) guidelines
 - Font sizes
 - Recent changes in labeling
- Understand your nutrient content claims (“low-fat” - - “high in Omega-3” - - “sugar free” - - others
- Determine presence of 8 major allergens and determine how to label for them
- Analyze the nutrient content of your food and properly state it on your nutrient facts panel
- Keep up with changes in regulation on marketing claims
- Understand the types of health claims that are allowed and not allowed and be prepared to offer scientific substantiation for your claims

Allergens

8 major allergens - - together account for 90% of all food allergies in the US

Each require labeling and must be declared on any processed food

Big 8

- Milk
- Eggs
- Fish
- Crustacean shellfish
- Tree nuts
- Peanuts
- Wheat
- Soya/soybean

Prevention and Labeling for Allergens

Why is Prevention and Labeling of Allergens Important?

- Because the consumer can only identify that the allergen is in the food by your label or packaging
- Placing their health and lives in your hands
- Labels protect
 - Consumers
 - Company from recalls
 - Regulatory scrutiny
 - Potential legal liability

Federal Food, Drug and Cosmetic Act (packaged food regulated under this act)

Food Allergen Labeling and Consumer Protection Act of 2004 (went into effect January 2006)

www.cfsan.fda.gov/~dms/algact.html.

USDA requires meat and poultry plants comply with programs designed to identify and prevent allergens (www.fsis.usda.gov/OPPDE/rdad/FRPubs/05-016N.htm)

Allergen Control Plan

Examples of a Control Plan

- Product Design and Development
- Segregation of Foods during Receiving, Storage, Handling and Processing
- Supplier Control Program for Ingredients and Labels
- Prevention of Cross-Contact During Processing
- Product Label Review and Label/Packaging Usage and Control
- Validated Allergen Cleaning Program
- Staff Training and Education
- Allergen Precautionary Labeling

Conclusion

Remember that your risks can fall into 5 general areas:

- Financial risk
- Marketing Risk
- Legal Risk
- Human Resources Risk
- Production Risk

Crop Insurance can help you address production risk and can address your financial risk of food production

General and specific liability insurance policies can address your legal risk, marketing risk, food safety risk and human resources risk

Insurance in modern times is a must in order to manage the full range of risks you have in being in food and food production - - particularly in a commercial marketplace



School of Law

Indigenous Food and Agriculture Initiative

The nation's first law school initiative focusing on Tribal food law and policy supporting food systems, agriculture and community sustainability

Janie Simms Hipp, J.D., LL.M. (Chickasaw)

Director

jhipp@uark.edu

(479)575-4699

Visit our website:

www.indigenousfoodandag.com

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