



2017

THE ALMOND CONFERENCE

SURVEYING THE LEGAL RISK LANDSCAPE

Room 314 | December 7 2017



AGENDA

- **Rebecca Bailey**, Almond Board of California, moderator
- **Jeff Gullickson**, Western Growers Insurance Services
- **Rachael Spiegel**, Faegre Baker Daniels LLP
- **Matt Bigham**, Western Growers Insurance Services



Food Safety: Surveying the Legal Risk Landscape

Rachael D. Spiegel

Attorney

Faegre Baker Daniels

2017 Almond Conference

December 7, 2017

FAEGRE BAKER
DANIELS

- Food Safety Modernization Act
 - ▶ Produce Safety Rules
 - ▶ Imports
 - ▶ Inspections
- Foodborne Illness Litigation
- Park Doctrine/Criminal Liability



- Food Safety Modernization Act: FSMA
 - ▶ Amends Food Drug & Cosmetic Act
 - ▶ Most sweeping changes since 1938
 - ▶ Focus is on prevention and **risk-based** analysis
 - Resources are limited, must be targeted
 - Some foods are riskier than others
- Law divided into three sections:
 - ▶ Preventive Measures
 - ▶ Detection and Response Measures
 - ▶ Imported Foods



- Covers anyone who manufactures, processes, stores or transports food
- Food safety plan (HARPC) for food facilities
- Produce safety rules for growers, packers
- Increased FDA powers – recalls, detention, suspension
- Increased inspections – focus on high-risk facilities
- Foreign supplier verification – importers must ensure FSMA compliance of foods sourced outside the US



- FSMA legislation was a response to “dangerous” **imported** foods and high profile **outbreaks**
 - ▶ melamine-contaminated wheat gluten from China
 - pet food
 - ▶ leafy greens
 - ▶ sprouts
 - ▶ peanut butter (twice)
 - ▶ eggs



- Typically handled and consumed raw
 - ▶ No kill step
- Susceptible populations
 - ▶ Elderly
 - ▶ Children
- Uncontrollable environment
 - ▶ Birds
 - ▶ Mammals
- Pesticides



FSMA's Produce Safety Rules

- FDA's "minimum standards for safe production and harvesting of" certain high-risk, raw agricultural commodities
- Priority to high risk produce with history of outbreaks



- Risk-based
- Examples:
 - ▶ Water
 - ▶ Soil amendments
 - ▶ Animal intrusion/buffers
 - ▶ Hygiene
 - ▶ Pest control
 - ▶ Temperature control
- Exempts facilities subject to HARPC requirement



- Foreign Supplier Verification
- Increased inspections of foreign facilities
- Increased border inspections and testing



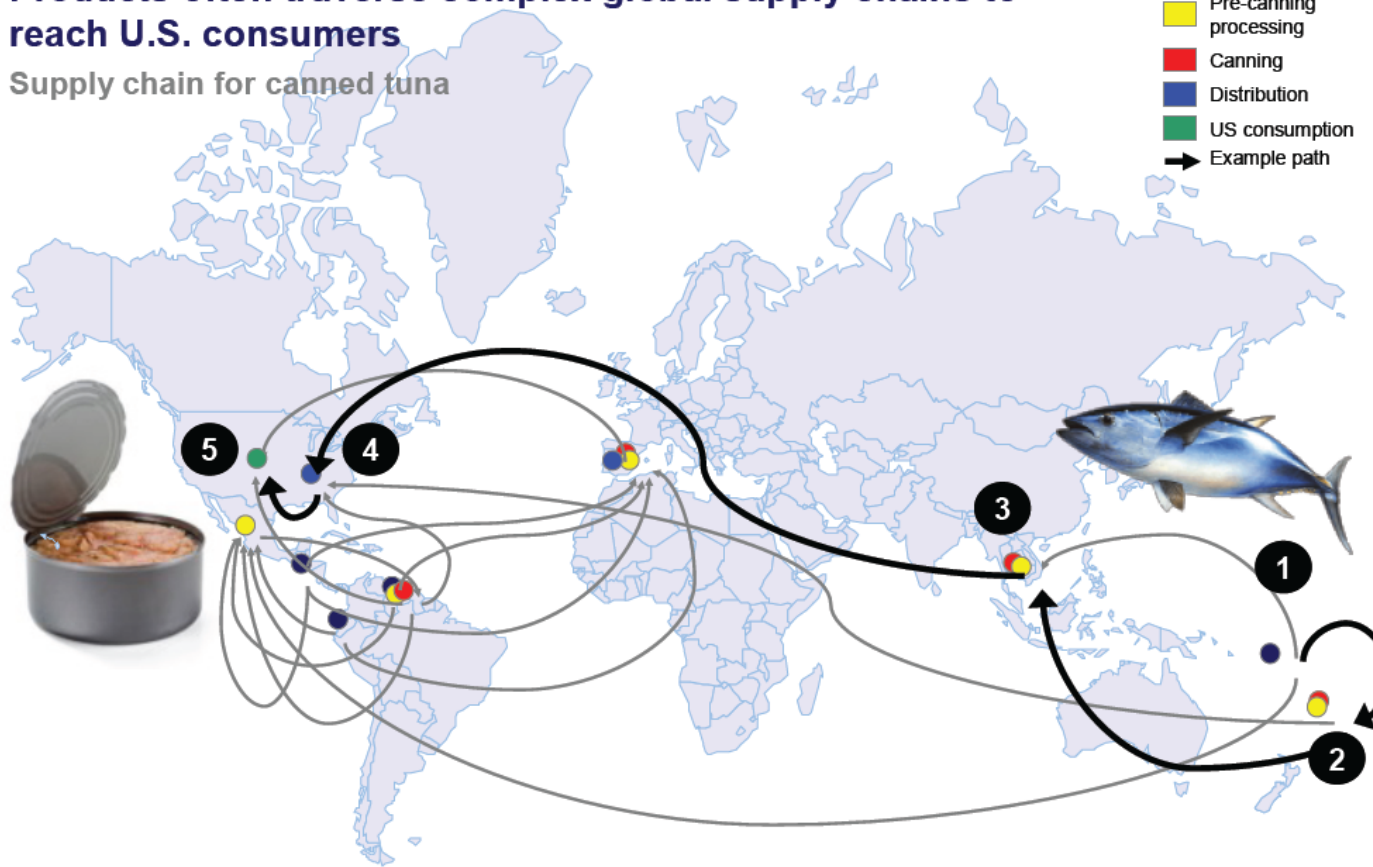
Exhibit 7 – Illustrative supply chain for canned tuna



Products often traverse complex global supply chains to reach U.S. consumers

Supply chain for canned tuna

- Processed into frozen pieces
- Pre-canning processing
- Canning
- Distribution
- US consumption
- Example path



- Importers must conduct risk-based foreign supplier verifications
 - ▶ Ensure compliance with food safety requirements
- Practical implications:
 - ▶ Spices/ingredients = higher risk = more diligence required of importers
 - ▶ Importer reputation is key to avoiding detentions at port, so properly vetting suppliers is key

- FDA & CBP to coordinate on inspecting imported foods
- Six basic factors:
 - ▶ Known safety risks of imported food
 - ▶ Known safety risks of country/region of origin, and through which food was transported
 - ▶ Compliance history of importer (outbreaks, recalls, violations)
 - ▶ Rigor/effectiveness of FSVP activities by importer
 - ▶ VQIP participation
 - ▶ Priority under FDCA § 801(h)(1)

Inspection of “High-Risk” Facilities



- FDA prioritizes inspection of “high-risk facilities”
- Factors FDA uses to determine “high-risk” facilities:
 1. Known safety risks of the food
 2. Compliance history of a facility
 3. Rigor and effectiveness of the facility’s HARPC
 4. Priority under FDCA 801(h)(1) (detection of intentional adulteration in imported food)
 5. Certifications for Imported Food
 6. Catch-all “Any other criteria deemed necessary and appropriate”

- Was a snapshot in time – now like to being more like an IRS audit
- Under FSMA now have access to:
 - ▶ Food Safety/HARPC Plan
 - ▶ Monitoring/verification records
 - ▶ Validation records
- Focus on systems and documents
- FDA will take **Product and environmental samples** – “swab-a-thon”



- What can FDA's environmental and product testing results be used for?
 - ▶ Identify an outbreak
 - ▶ Litigation – prove source of outbreak or contamination



New Testing Technology: WGS

- Regulatory and public health agencies are using Whole Genome Sequencing (WGS) technology
- WGS is more accurate than PFGE
 - ▶ WGS analyzes a pathogen's entire DNA sequence
 - ▶ PFGE analyzes less than 1% of a pathogen's genome
- Easier to pinpoint source of a foodborne illness outbreak and link back to a producer or field
- FDA has created a new WGS database



- WGS credited for determining source of smaller, ongoing outbreaks



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

“Whole Genome Sequencing Is The Biggest Thing To Happen To Food Microbiology Since Pasteur Showed Us How To Culture Pathogens...”



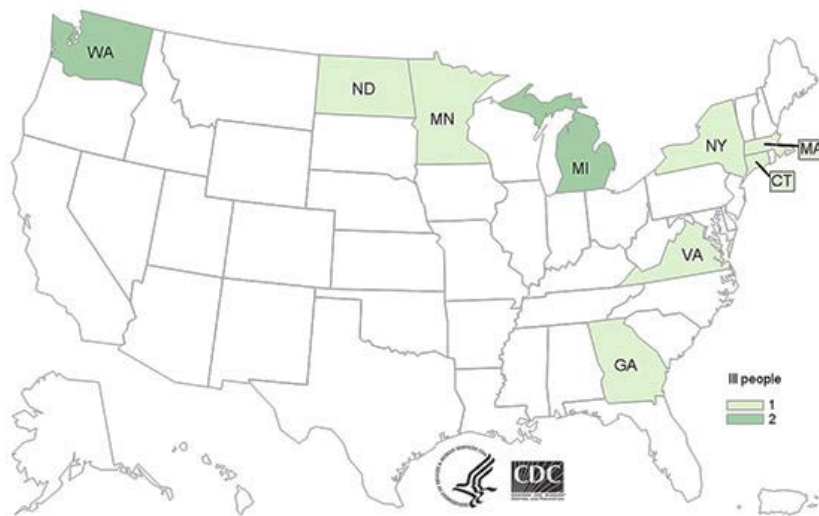
*~Dr. Jorgen Schlundt
Exec Director and Founder
The Global Microbial Identifier*



- Random sample of product matched listeria patterns in PulseNet database
- Inspections of plants included environmental swabs
- WGS results linked to 10 illnesses over 5 years, including 3 deaths
- Rolling recalls
- Lawsuits filed
- Plants shut down



- March 2016 Salmonella outbreak linked to pistachios
- 11 people sick across 9 states; 2 hospitalized



More Testing = More Information



- Who has access?
- What can it be used for?
 - ▶ Identify high-risk facilities under FSMA
 - ▶ Identify contamination in plant or product, resulting in more recalls
 - ▶ **Litigation – prove source of outbreak or contamination**



Foodborne Illness Causes of Action



- Strict Liability
- Negligence
- Negligence Per Se
- Breach of Warranty
- Consumer Fraud/
Deceptive Trade Practices

23
3/1/2008

ROBERT H. GOLD (STATE BAR NO. 10420)
GOLD & ASSOCIATES
584 Castro Street, P.O. Box 480
San Francisco, CA 94114
Telephone: (415) 337-8670
Facsimile: (415) 337-0633
Attorney for Plaintiff

FILED
SAN MATEO COUNTY
OCT 1 5 2008
Clerk of Superior Court
By: [Signature]

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN MATEO

Case No. CIV 080718

Plaintiff

SEVENTH AMENDED COMPLAINT FOR:

1. NEGLIGENCE MISREPRESENTATION, REGARDING STUDENT LIFE INSURANCE REPAYMENT PROGRAM, ORALLY PROMISED AS A SIGN-ON BONUS (NONE) (a/b)

2. SEX DISCRIMINATION, (Pregnancy Discrimination and Non-Accommodation, all Defendants)

3. SEXUAL HARASSMENT (All Defendants)

4. FALSE LIGHT (Defendant) (All Defendants)

5. VIOLATION OF CALIFORNIA CIVIL CODE SEC. 56 et. Seq. (Publication of Medical Records, All Defendants)

6. VIOLATION OF THE CALIFORNIA CONSTITUTION (All Defendants)

7. WRONGFUL TERMINATION BY VIOLATION OF PUBLIC POLICY (All Defendants)

8. INTENTIONAL INFLECTION OF EMOTIONAL DISTRESS (All Defendants)

JURY TRIAL DEMANDED

GOLD & ASSOCIATES
ATTORNEYS FOR PLAINTIFF
PREPARED AND FILED BY
TAMARA R. JAVIER (SJD)

SEVENTH AMENDED COMPLAINT
- 1 -

Product was
defective



Defect caused
injury



Focus is on the ***product***, not fault or negligence

When Is a Product Defective?



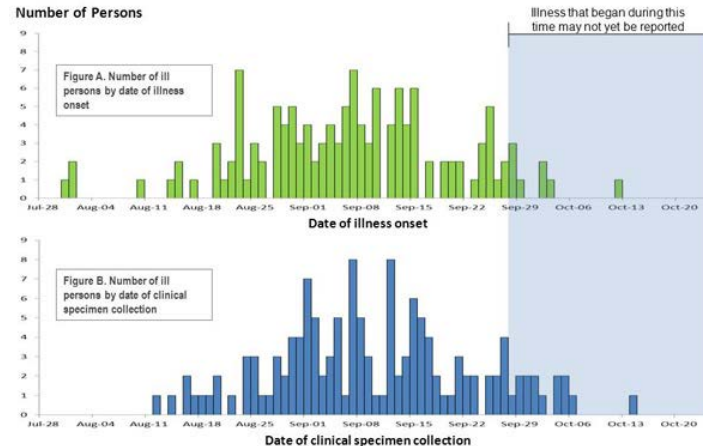
Consumer Expectation Test

“A reasonable consumer would not expect the food product to contain the harm-causing ingredient.”

-Restatement 3d, Torts: Products Liability § 7

Why Is It Easy to Prove Defect and Causation?

- CDC and Health Departments classify cases as **CONFIRMED**
 - ▶ Laboratory testing (PFGE or WGS)
 - ▶ Epi-linked
- Causation established
 - ▶ Product identification
 - ▶ Pathogen caused illness



- Anyone “engaged in the business of selling or otherwise distributing” the defective food product

-Restatement 3d, Torts: Products Liability § 7



Who Is Most Likely to Be Sued?

- a) Last in the chain of distribution
- b) Best known (brand name)
- c) Deepest pocket
- d) **All of the above**



“Without question, the single best weapon in the plaintiff’s arsenal in a foodborne illness case is the strict liability claim.”

Bill Marler, *Serving Up
Trouble*, Trial, Vol. 45, No. 2
(Feb. 2009)

Seller's Exceptions Statutes

- Vary from state to state
- Generally, seller is not liable if:
 - ▶ Producer is solvent and subject to jurisdiction
 - ▶ Seller exercised no control over design or manufacture
 - ▶ Product was sold in a sealed container
 - ▶ Product was not sold under seller's name
 - ▶ Seller has no knowledge of the defect
- Result: **Liability moves back up the supply chain to the grower**



Criminal Liability Under the FDCA



- Prohibited acts under the Federal Food Drug & Cosmetic Act (FDCA):
 - ▶ Introducing any adulterated or misbranded food in interstate commerce
 - ▶ Introducing, delivering, or receiving adulterated or misbranded food in interstate commerce



FSMA's Heightened Enforcement Climate

- FSMA gave FDA authority to criminally prosecute “**anyone**” in the manufacturing, labeling or distribution process
- Expanded criminal sanctions under the FDCA
 - ▶ If the offense results in serious illness, “the person committing the violation shall be imprisoned for not more than 5 years” and not more than 10 years if death results
- Added civil penalties
 - ▶ “Not more than \$1,000,000 for each offense” and every day is a separate offense.

Park Doctrine (Responsible Corporate Officer Doctrine)

United States v. Park, 421 U.S. 658 (1975)

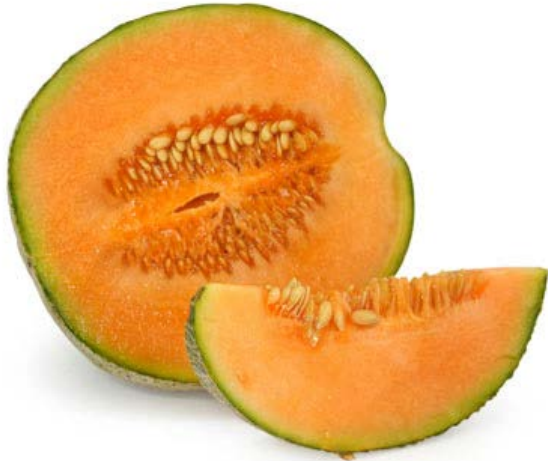
- U.S. Supreme Court held “[t]he [FDCA] imposes upon persons exercising authority and supervisory responsibility reposed in them by a business organization not only a positive duty to seek out and remedy violations but also, and primarily, **a duty to implement measures that will insure that violations will not occur.**”



Misdemeanor Strict Criminal Liability under FDCA

- A corporate official can be convicted of a misdemeanor based solely on his or her position of responsibility and control to prevent the underlying violation of the FDCA
- No requirement that the official acted personally in the wrongdoing or even had knowledge of it
- Misdemeanor convictions punishable by not more than one year or fines of not more than \$250,000, or both

Jensen Farms Listeria Outbreak and Recall



- 2011 Listeria outbreak involving cantaloupe grown by Jensen Farms
- 33 died, 1 miscarriage, 147 hospitalized
- Linked to inadequate washing system
- Jensen Farms audited only months before the outbreak and given “superior” (96%) rating

Jensen Farms Civil Litigation



- Lawsuits filed
- Company declares bankruptcy
- Plaintiffs receive some money through bankruptcy claim valuation process
- Plaintiffs' lawyers sue distributor Frontera Produce and retailers like WalMart and Kroger
- Plaintiffs' lawyers also sue third-party auditors



Jensens' Criminal Prosecution

- Eric and Ryan Jensen arrested and charged with 6 misdemeanor counts as “responsible corporate officers”
- Each faced up to 6 years in prison and \$1.5 fine
- Sentenced to 5 years probation, 6 months home detention, and \$150,000 each in restitution to victims
- Lack of knowledge or intent, reliance on audit was no defense
- Prosecution: “Message of deterrence to the food industry.”



What Can You Do Now?

- Address the Basics
 - ✓ Compliance programs at all levels
 - ✓ Create a culture of food safety
 - ✓ Don't wait on FSMA requirements
 - ✓ Don't rely solely on audits
 - ✓ Keep good records
 - ✓ Train employees
 - ✓ Prepare (and practice) for inspections
 - ✓ Review and **practice** recall and crisis management plans
 - ✓ Make use of industry and trade group resources and services





- ✓ Do your facilities qualify as high-risk?
- ✓ What risks do the commodities you sell (and who you sell them to) present?
- ✓ Trust, but verify, your suppliers food safety practices (don't necessarily rely on audits, certifications)
- ✓ Review contractual requirements for indemnity and insurance
 - ▶ Your suppliers
 - ▶ Your customers
- ✓ Keep up-to-date on your industry and food safety issues

- FDA Food Safety Modernization Act (FSMA)
 - ▶ <http://www.fda.gov/Food/GuidanceRegulation/FSMA/>
- FDA Inspections, Compliance, Enforcement, and Criminal Investigations
 - ▶ <http://www.fda.gov/ICECI/>
- Western Growers, Science & Technology
 - ▶ <https://www.wga.com/services/sci-tech>
- Rachael Spiegel, Faegre Baker Daniels LLP
 - ▶ <http://www.faegrebd.com>

Rachael D. Spiegel
Attorney | Minneapolis

T: +1 612 766 7850

Rachael.Spiegel@FaegreBD.com



Thank you!



Research Poster Sessions

Wednesday, December 6

3:00 p.m. – 5:00 p.m.

Featured topics:

- Irrigation, nutrient management
- Breeding
- Soils, if related to organic matter input
- Sustainability, irrigation improvement continuum, life cycle assessment, dust
- Food quality and safety

Thursday, December 7

1:30 p.m. – 2:30 p.m.

Featured topics:

- Insect and disease management
- Fumigation and alternatives
- Biomass (including biochar-related efforts)
- Pollination
- Almond Leadership Program

What's Next

Thursday, December 7 at 12:00 p.m.

- Luncheon Presentation – Hall C

Innovative Plant-Based Foods – An Awesome Future for the California Almond Business

Speakers: John Haugen and Tal Ronnen, Kite Hill

Luncheon is ticketed and is sponsored by Moss Adams

