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Christopher G. Van Gundy Partner Keller and Heckman LLP



Arthur S. Garrett III Partner/General Counsel Keller and Heckman LLP

Terminology

- Quality
- Authenticity
- Adulteration
- Food Fraud



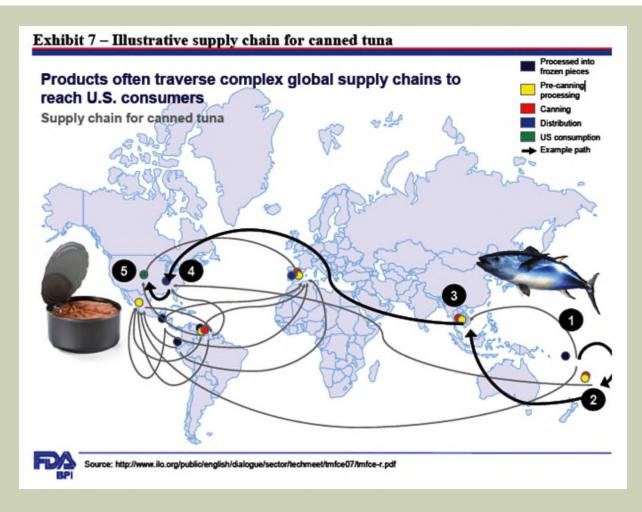
Elliott Review into the Integrity and Assurance of Food Supply Networks – Final Report

A National Food Crime Prevention Framework

July 2014

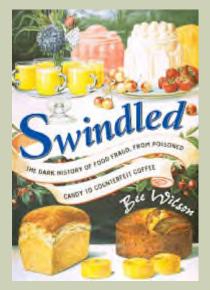
Economically Motivated Adulteration





- "Food Fraud" Has Been Around For A Long Time
- Conventional Wisdom Little Awareness
- Food Authenticity Issues Are To Be Expected
- US Alone In Not Seeing Food Safety Tie







US GOV'T IS "BEHIND" OTHER COUNTRIES



Top Ten List

Government enforcement actions (e.g. seizures)

Canada

FSIA Testing/Enforcement

> UK

Food Fraud Advisory Unit

China

- Melamine scandal
- □ Food fraud = food safety



Common Elements Of Food Authenticity Issues

- High margin product
 - Not easy to manufacture
 - Perceived health or nutritional benefits
- Lack of (enforced) "standards of identity"
- Supply shortage
- Gap between consumer demand/knowledge
- Detection is difficult for consumers
 - **Fraud is one step ahead of the experts**



- "Food Fraud" Programs At U.S. Universities
- There Is A EU Parliament "Top Ten" List:
 - Olive oil
 - Fish
 - Organic foods
 - > Milk
 - Grains
 - Honey and maple syrup
 - Coffee and tea
 - > Spices
 - > Wine
 - Certain fruit juices







Food Fraud Initiative

- Big Loss of Business
 - \$10B to \$15B per year (GMA)
 - Harm to Reputation
- Product Categories Can Be Damaged
 - Lost Profits PLUS
 - Increased Liability Exposure
- Food Safety
 - Undisclosed Allergen
 - **Cumin**
 - Hazard Analysis
 - Pomegranate arils





Recalls

- Competitors/Partners
- District Attorneys



- Consumer Class Actions in "Food Court"
- State Attorneys General



- Recalls
 - Cumin
- Competitors
 - Lanham Act
 - POM v. Coke





District Attorneys Chlorophyll in Olive Oil



The "Food Court"

- Nickname given to Northern California federal courts because of all the class action food cases
- "This district has seen a flood of such cases . . ." (Judge Breyer, June 13, 2014)

Since 2012....

- 200+ consumer food class actions in USA
- 100+ of these are in California
- Florida and New York, too
- 25 of these cases have settled with a wide range of dollar values, relief and class distribution
- 60 cases have been dismissed at various stages 12(b), summary judgment and class certification/decertification

The Food Court – Cont'd

- Single state, multistate, or national purported classed
- Claims for class-wide damages, injunctive relief
- For misrepresentations regarding food content or labeling
 - "All Natural"
 - Organic
 - Evaporated Cane Juice
 - GMO's
 - "Food Fraud"



Purported Consumer Class Actions

- Kumar v. Safeway, Inc., Case No. RG14726707 (Ala. Co. Sup. Ct. May 20, 2014);
- Koller v. DeOleo USA, Inc.; and Med Foods, Inc., Case No. 3:14-cv-02400-EDL (N.D. Cal. May 23, 2014);
- Kumar v. Salov North America Corp.; and Italfoods, Inc., Case No. 4:14-cv-02411-YGR (N.D. Cal. May 23, 2014).





State Attorneys General

- Herbal supplements
- Undisclosed allergens
- Retailers were the focus
- Liability couldn't be passed on to suppliers
- GNC settlement testing protocols
- Aggressive use of DNA barcoding technology
- FDA GMP compliance not enough
- Copycat consumer litigation



FDA Enforcement Actions

- "Voluntary" and mandatory recalls
- Warning Letters
 - Published
 - **Can lead to further enforcement actions, like seizure**
- Administrative Detention
- Import Alerts
- FSMA
 - **Foreign supplier verification**



- Inspections abroad
- Criminal liability for misbranding, adulteration
 - Recall often first step
 - **\$11** million fine/guilty plead for salmonella in peanut butter
 - Park doctrine





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Import Alert 22-04

FDA Home Import Program Import Alerts Imports Alerts by Number Import Alert

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 22-04 Published Date: 03/24/2015 Type: DWPE

Import Alert Name:

"Detention Without Physical Examination of Juices and Juice Concentrates that are Adulterated or Misbranded Due to Substitution."

Reason for Alert:

NOTE: The revision to this import alert dated 03/21/2014 revises the Import Alert name to now include all juice and juice concentrates that may be adulterated or misbranded due to substitution. In addition, the reason for alert has been updated to include 100% juice, the guidance section has been updated to alert the field where to send cases and the product codes and product descriptions have been expanded. Lastly, a new PAF and charge code have been added.

*** The Center for Food Safety and Applied Nutrition (CFSAN), received several written complaints from U.S. firms and attorneys alleging that imported juices and juice concentrates such as pomegranate juice and lemon juice did not meet the label declaration of 100% juice. It has been claimed that the juice has been substituted with other substances, such as citric acid or sweeteners. The complainants alleged that they, or their clients, were competing at a disadvantage resulting in an economic loss. ***

FDA conducted its own sampling in follow-up to the complaints. After the analysis, FDA found that some of the samples contained undeclared ingredients (e.g., artificial colors, citric acid, sweeteners, or less expensive juices that substitute in whole or in part for the juice purported on the label) so the products were not as they were represented to be on the labels and were therefore adulterated and misbranded.

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Lessons Learned From Goknur

- Where it can happen, it will happen
 - **Supply shortage**
 - High margins
 - Not easy to make pomegranate juice or arils
 - Principles of food fraud confirmed
- Harm to competition
 - Lost profits
 - Harm to category
- Also harm to consumers
 - Extra sugar
 - Health benefits diminished/lacking
 - **Everybody in the supply chain was "ripped off"**
- Fraud and food safety are connected
 - Hepatitis A outbreak in pomegranate arils (seeds)
 - Huge supply chain liability and mess





Combatting Food Fraud

- USP Guidelines
- Food Fraud Databases
 - www.foodshield.org
 - USP



- Supply Chain Analysis
 - Attorneys, Industry Consultants, Scientists
 - Risk Assessment and Mitigation
 - Proper Tests, Protocol

- Litigation
- Retailer Programs
- Third-Party Accreditation
- FSMA Compliance
- GFSI Mitigation Measures
- Insurance?





Role Of Counsel

- Each supply chain is unique
- Experienced food litigation counsel know:
 - the applicable legal standards
 - the "fraud"
 - the unique challenges in the industry
- Expertise in selecting expert witnesses
- Developing litigation proof protocols
 - Implementing proper protocols
 - **FDA** compliance
 - Supply chain protections/messaging
 - **FDA** guarantees
 - "We're checking"
 - □ Appropriate insurance procurements/coverage





FOOD FRAUD INSURANCE?

- Food Fraud is essentially the false advertising, labeling and marketing of a food product.
 - In other words, the food is not what it says it is or what you think it is.
 - Whether a company has insurance coverage depends on the type of "Food Fraud" claim being made.

FOOD FRAUD CLAIMS

- Coverage will depend on the type of Food Fraud claim alleged:
 - Lanham Act Claim (false designation of origin, false description)
 - California CLRA Claim (deceptive advertising)
 - Breach of Contract Claim (economic Loss)
 - Bodily Injury Claim (consumer injured)
 - Property Damage Claim (fraudulent food ingredient "inextricably intertwined" in food product)

INSURANCE POLICIES

Third-Party Liability Policies

- CGL Policy
- D&O Policy
- E&O (media)/Professional Liability Policy
- First-Party Policies
 - Property Insurance
 - Specialized Recall Policy (Product Contamination Insurance)

LANHAM ACT CLAIM

- Lanham Act False Advertising claim
 - CGL Policy
 - Coverage for "Advertising Injury"
 - Misappropriation of Advertising Idea
 - Infringement of Another's Slogan
 - Disparagement of another Product
 - Exclusions (nonconformity, violation of statute)
 - **D&O**



CALIFORNIA CLRA CLAIM

CGL Policy

Coverage for "Advertising Injury"

- Misappropriation of Advertising Idea
- Infringement of Another's Slogan
- Disparagement of another Product
 - Exclusions (nonconformity, violation of statute, knowledge of falsity)
- D&O "wrongful act"
- E&O (media) coverage for errors and omissions in "content"

BREACH OF CONTRACT CLAIM (ECONOMIC LOSS)

CGL Policy

Has to be Bodily Injury or Property damage

Does not Cover Breach of Contract

- Exclusions (recall exclusion, warranty exclusion)
- D&0/E&0
- Recall Policy
 - 3rd-party liability



BODILY INJURY CLAIM

- BI Claim injury due to ingestion of cumin cut with almonds or melamine in baby food
 - CGL Policy



- Defense and Indemnity
 - May not cover emotional distress
- D&O/E&O (BI exclusions)

PROPERTY DAMAGE CLAIM

- PD Claim -- fraudulent food ingredient "inextricably intertwined" in food product
 - CGL Policy (defense and indemnity)
 - Property Policy (first-party) contaminated "stock"





THANK YOU!

Christopher G. Van Gundy

Partner Keller and Heckman LLP Three Embarcadero Center, Suite 1420 San Francisco, CA 94111 415-948-2831 vangundy@khlaw.com

Arthur S. Garrett III Partner/General Counsel Keller and Heckman LLP 1001 G Street NW, Suite 500 West Washington, DC 20001 202.434.4248 garrett@khlaw.com



Christopher G. Van Gundy Partner Keller and Heckman LLP



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