

A hand in a white shirt is carefully balancing a wooden block on top of a tall, wobbly stack of wooden blocks, resembling a Jenga tower. The background is dark and out of focus.

Managing Risk in the Food & Beverage Industry

Seminar & Panel Discussion

Wednesday, December 5, 2018 · 7:30am - 11:30am

WELCOME AND INTRODUCTION

Robert J. Heinrich

Chair of Reinhart's Food and Beverage Law Practice Group
Shareholder in Reinhart's Banking and Finance Practice

Food & Bev is Big Business in Wisconsin

- 1,400 companies in food and beverage processing
- 93,000 industry jobs
- \$67.8 billion in annual food processing industrial sales
- Dairy
 - #1 in cheese production
- Organics
 - #1 in organic production of corn, oats, beans and hay acreage
- #1 in food product machine manufacturing

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Reinhart's Food & Bev Practice Group

- Attorneys from all practice groups -- for example:
 - Transactional
 - Litigation
 - Product distribution and franchise
 - IP
 - Real estate
- Clients range from start-ups to established middle market (and larger) companies
 - Manufacturers, retailers, wholesalers, restaurants, breweries, wineries, distilleries, franchisors and entrepreneurs

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Food & Bev Industry Faces Unique Legal Issues

- Recalls
 - Increasing in frequency
 - Very high profile
- Labeling
 - Desire to promote healthy and natural products can lead to heartburn

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Recall Planning

Best Practices in Preparing for the Worst

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Lesson One: It is *Always* Bad Timing

It is the afternoon of December 23rd. You are preparing for a few days off for the holidays when your quality assurance manager calls you. A routine review of the past week's production records indicates that certain of your dairy's products which recently shipped may have been insufficiently processed to kill pathogens present in raw milk, including *Salmonella*, *Campylobacter*, *Listeria*, and/or *E. coli*. A recall may be necessary.



WHAT DO YOU DO NEXT?

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Be Prepared to Act *Quickly*



Your mind immediately turns to several key questions:

- ✓ What do we know?
- ✓ What is the scope of product involved?
- ✓ Who from the company should be in the loop?
- ✓ Who do we need to notify and how should we go about it? Customers? Regulators? Consumers?
- ✓ What about insurance?

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What Might Prompt a Recall?

- Contamination or Adulteration
 - Microbial (*i.e. Salmonella, Listeria, E. coli*)
 - Foreign material
 - Chemical
 - Pesticide/herbicide/fungicide
- Tampering or Intentional Contamination (in-house or external)
- Misbranding
 - Allergens
 - Nutrients
 - Ingredients
 - Mislabeling
- Packaging defects/errors
- Failure to conform to Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Points (HACCP) Plan

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FDA Definitions

CLASS I RECALL: A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death (must be reported to the FDA Reportable Food Registry regardless of their point of origin).

CLASS II RECALL: A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III RECALL: A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

MARKET WITHDRAWAL: Occurs when a product has a minor violation that would not be subject to FDA legal action and would not cause adverse health consequences. The company removes the product from the market or corrects the violation.

Critical Considerations

- Getting a Clear View of the Scope
- Relationship with Regulators
 - Be the initiator and then the cooperator.
 - Keep them informed and do what you said you would do.
- Get Legal Involved
- Timely notice to insurers
- Supply Chain Management
 - What are your contract terms with suppliers? With customers?
- Clear and Timely Communications
 - With regulators, with your supply chain, with the public.

How to do this? **HAVE A WELL CRAFTED PLAN.**

Having a Plan

- According to the [Food Safety Modernization Act \(FSMA\) Final Rule for Preventive Controls for Human Food](#): “If the hazard analysis identifies a hazard requiring a preventive control, the facility must have a written recall plan that describes the procedures to perform a recall of the product.”
- At minimum, the recall plan must include procedures to notify consignees, to notify the public when necessary, to conduct effectiveness checks and to appropriately dispose of recalled product.

What Should Be in the Plan?

- Identification of recall team members (with *complete* business and after-hours contact information)
- Process for identifying the problem and determining the significance and scope of the hazard
- Communication plan for regulatory agencies, customers, consumers
- Procedure for removal, disposition, and replacement of product
- After-action evaluation procedure

Assembling Your Team

- ✓ Senior management
- ✓ Recall coordinator
 - Probably QA manager or senior operations manager
- ✓ Legal
- ✓ Production
- ✓ Logistics/Distribution/Supply
- ✓ Scientific Advisor
- ✓ Sales/Marketing
- ✓ Financial/Accounting
- ✓ PR/Consumer Affairs
- ✓ Information Systems



- Depending on the size/scope of your recall, you might want to consider using an outside recall coordinator.

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Problem Identification and Evaluation

- Procedures for promptly gathering and reviewing information to determine significance and scope of problem
 - Production, quality control, maintenance, sanitation records
 - Shipping records and product tracking
- Recall plan should anticipate potential product recall concerns
- How will testing be conducted, if necessary?



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Communication Plan

- What must be communicated and when?
- Who is responsible for each communication?
- Templates for recall communications (internal, consignees, state/federal regulatory agencies, media)
- Letter drafts (agency notifications, customers/consignees)
- Telephone scripts for calls to customers/consignees (retailers, wholesalers, distributors)



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Process for Product Removal and Disposition

- How will you locate, hold and quarantine the problematic product?
- How will you retrieve and dispose of the product, or will you direct others in your customer chain to do so?
- What steps will you take to clear your facility to resume production?
- Instructions on disposition should be clear and unambiguous
- Careful recordkeeping and effectiveness checks



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After Action Reporting and Evaluation

- Plan for post-recall evaluation of the process
- Include customers/consignees in the evaluation process
- Document lessons learned and update the recall plan accordingly

Revisiting our Recall Scenario

- In the case of the dairy with potentially under-processed product, if there were a risk of microbial contamination, then the product could present life-threatening risk
- The recall team would follow the recall plan in:
 1. Identifying the affected product, ceasing distribution and determining the extent of distribution;
 2. Notifying the FDA and making a report to the Reportable Food Registry;
 3. Notifying customers/consignees and retrieving the recalled product.



HEALTH

Boise Meadow Gold plant recalls several dairy products

Meadow Gold Dairy in Boise Conducts Voluntary Recall of Whipping Cream and Half and Half Because of Possible Health Risk

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Takeaways

- If your process includes a hazard requiring a preventative control, FSMA requires a documented recall plan
- A carefully prepared recall plan will put your company in position to protect consumers, preserve its public image and customer relationships, and maintain positive relations with regulators.

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Questions?



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TRENDING TOPICS IN FOOD LABELING LITIGATION

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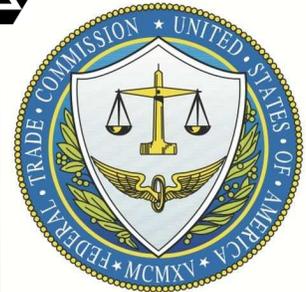
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Labeling and Advertising Law Overview

- Regulated by:
 - FTC, FDA, state statutes
- What do they do?
 - FTC: prohibits false or misleading **advertisements**
 - FDA: prohibits false or misleading **labeling**
 - State/federal statutes: prohibit unfair competition, misleading statements, false advertising, etc.
- Why care?
 - Hundreds of claims filed each year
 - Enforcement activities (FDA, FTC), private consumer actions, state AGs, competitor claims (NAD, Lanham Act)



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Labeling Claims to Watch For

- Category names/groupings
 - Healthy
 - Natural
 - GMO-free
 - Organic
 - Made in the USA
- Use of names and groupings



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Labeling Claims to Watch For (cont.)



- Use of names and groupings
 - Aisle names
 - In-store circulars
 - Point-of-sale materials
 - Website sales and advertising
 - TV, radio, and print advertising

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Hot Topics in Food Labeling

- Organic claims (Organic Foods Production Act (“OFPA”)) establishes national standards for organic production and food labeling
- Includes 100% organic, organic, made with organic ingredients



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Hot Topics in Food Labeling (cont.)

- Natural claims
 - Not currently defined by FDA
 - FDA comment period started November 2015
 - One of the most litigated food label claims currently
 - Unclear guidance
 - Consumer expectation of natural
 - Non-GMO
 - No artificial flavors/colors/ingredients



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Hot Topics in Food Labeling (cont.)



- Non-GMO/GMO-Free claims
- FDA declined to require GMO labeling until July 2016, directing USDA to create mandatory labeling program requiring:
 - disclosures of GMO on package text;
 - USDA-created symbol; or
 - bar codes or other digital means that consumer can scan
- USDA will likely finalize its rules in December 2018

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Hot Topics in Food Labeling (cont.)

- Healthy
 - FDA defines “healthy” as foods:
 - low in fat
 - low cholesterol
 - low sodium
 - contains at least 10% of one or more qualifying nutrients
- FDA rules in flux (May 2016 Kind decision) due to Kind’s challenge to healthy claims (*i.e.*, whether it was a lifestyle label and not commentary on nutritional content)



Questions?



Thank You!

ALLERGENS AND ADVISORY LABELING

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- Milk



- Eggs



- Fish



- Crustacean shellfish



- Tree nuts



- Peanuts



- Wheat



- Soybeans



The Eight Major Allergens

21 U.S.C. § 321(qq)

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Labeling for Allergens

- The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requires that the label disclose the presence of the allergen. 21 U.S.C. § 343(w).
- Two options:
 - The word "Contains," followed by the name of the food source from which the allergen is derived, immediately after or adjacent to the ingredients
 - Contains: wheat, soy
 - The common name of the allergen in the required list of ingredients, followed in parentheses by the name of the food source from which the allergen is derived
 - **Ingredients:** Sugar, flour (wheat), whey (milk)...
- The FDA prescribes very specific requirements; check the statute and the available guidance
 - For example: In a "Contains" statement, the "C" must be capitalized, but the use of bolding and punctuation is optional

Cross-Contact

- In a number of food products, the eight major allergens aren't intentionally added, but they may be present due to the conditions under which the products are manufactured
- This used to be known as "cross-contamination"; now, it's frequently called "cross-contact"
- Occurs when equipment is shared, utensils are shared--sometimes even when an ingredient is present in the same space (for example, traces may travel through the air)
- This takes us into a gray area: how to disclose the *possible* presence of the allergen?

Cross-Contact Could Render the Product Adulterated

- According to the FDA, FALCPA and its labeling requirements do not apply to cross-contact
- But under 21 U.S.C. § 343(a)(4), a food is adulterated if it "has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or *whereby it may have been rendered injurious to health...*"
- The FDA has long taken the position that this provision applies to allergen cross-contact; it recently made that explicit in updates to the regulations, adding the prevention of "allergen cross-contact" as a benchmark for the adulteration analysis
 - *E.g.*, 21 C.F.R. § 117.35(a): cleaning and sanitizing of utensils and equipment must be conducted in a manner that "protects *against allergen cross-contact* and against contamination of food..."

Disclosing as an Ingredient Could Be Misbranding

- Under 21 U.S.C. § 343(a), a food is misbranded if "its labeling is false or misleading in any particular..."
- Disclosing an allergen as an ingredient, when it may *not* be present, could be considered misbranding

Disclosing as an Ingredient Could Be Misbranding (cont.)

- FDA Warning Letter to Chocolates Garoto S.A. (Aug. 3, 2015):
 - Product label included a “Contains” statement: “Contains traces of peanut, hazelnut, cashew nut and brazil nut.”
 - “The ‘Contains’ statement must include the food sources of all major food allergens that are ingredients or are contained in ingredients used to make the finished food. FALCPA does not permit the use of a ‘Contains’ statement for major food allergens that are not intentionally added to the food.”

Disclosing as an Ingredient Could Be Misbranding (cont.)

- FDA Warning Letter to Beech-Nut Nutrition Corporation (Feb. 22, 2010):
 - Label for Whole Grain Oatmeal and Mixed Fruit cereal included a statement “Contains Wheat.” The ingredients statement on the label did not include wheat.
 - “The presence of an allergen ‘Contains’ statement may be confusing or misleading to consumers if the product does not contain an allergenic ingredient.”

Advisory Labels

- A large number of manufacturers use *advisory labels* to disclose potential cross-contact
 - “May contain milk”
 - “May contain traces of wheat and soy”
 - “Processed in a facility that also processes tree nuts”
 - “Processed on a line that also processes products containing peanuts”

Advisory Labels (cont.)

- At present, advisory labeling is not regulated by the FDA
- Guidance comes from a June 10, 1996 Notice to Manufacturers: “Label Declaration of Allergenic Substances in Food” (predates FALCPA)
 - “The agency is aware that some manufacturers are voluntarily labeling their products with statements such as ‘may contain (insert name of allergenic ingredient).’ FDA advises that, because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMP.”

Advisory Labels (cont.)

- Further guidance:
 - *Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance (Oct. 2006)*
 - “FALCPA does not address the use of advisory labeling, including statements describing the potential presence of unintentional ingredients in food products resulting from the food manufacturing process. ... In earlier guidance, FDA advised that advisory labeling such as ‘may contain [allergen]’ should not be used as a substitute for adherence to current Good Manufacturing Practices (cGMPs). In addition, any advisory statement such as ‘may contain [allergen]’ must be truthful and not misleading.”

Advisory Labels (cont.)

- Advisory labels are permissible but not required--at least not by FALCPA
- They must be truthful and not misleading
- They can't substitute for GMPs and will not inoculate a manufacturer against a finding of adulteration based on allergen cross-contact
- So far, FDA has declined to set an allergen threshold beyond which a product is considered adulterated. (It has also declined to establish an “absolutely allergen-free” standard.)

What to Do

- In the absence of further guidance, it's better to use advisory labels than not
 - Best serves objective of consumer protection
 - Use a simple label that clearly communicates the potential presence of the allergen in the finished product
- GMPs are critical. Don't think that an advisory label renders cross-contact a non-issue.
- Be cognizant of other claims that may suggest to consumers that your product is allergen-free; this could mislead consumers, even when coupled with an advisory statement

Additional Sources

- U.S. Food & Drug Administration, *Frequently Asked Questions about Food Allergies*, U.S. DEPT OF HEALTH AND HUMAN SERVICES, <https://www.fda.gov/food/ingredientpackaginglabeling/foodallergens/ucm530854.htm> (last visited November 16, 2018).
- U.S. Food & Drug Administration, *Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance*, U.S. DEPT OF HEALTH AND HUMAN SERVICES, <https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm059116.htm> (last visited November 16, 2018).
- U.S. Food & Drug Administration, *Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers*, U.S. DEPT OF HEALTH AND HUMAN SERVICES (June 10, 1996), available at <http://wayback.archive-it.org/7993/20170111004312/http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106546.htm>.

Questions?



Thank You!

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HOT TOPICS IN FOOD LABELING: CALIFORNIA PROPOSITION 65

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Proposition 65

- California Safe Drinking Water and Toxic Enforcement Act of 1986
 - Directly approved by voters in a ballot initiative
 - A warning regime
 - Key goal: informing consumers of risks of cancer and reproductive harm due to exposures to specific chemicals

Proposition 65 (cont.)

- "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual"
 - "Intentionally" not defined
 - "Knowingly" refers to knowledge of fact of exposure

Why Proposition 65 Matters to Out-of-State Manufacturers & Distributors

- Citizen suits: cottage industry for environmental advocates and plaintiffs' firms
- Defendants at a significant disadvantage in defending against Proposition 65 claims
- Average settlement cost: \$100,000

Why Proposition 65 Matters to Out-of-State Manufacturers & Distributors (cont.)

- Over 16,000 Proposition 65 claims filed since enactment
- 2017 - 688 Proposition 65 claim settlements
 - Total settlements: < \$25 million
 - Civil penalties: \$4,843,142
 - Attorneys' fees: \$19,486,362 (76% of total)

What Chemicals Require Warnings?

- Over 900 listed chemicals
 - <http://oehha.ca.gov/proposition-65/proposition-65-list>
- List updated annually
 - State qualified experts: scientists and health professionals
- 12-month grace period for newly-listed chemicals
- Some chemicals may be delisted as risk of cancer or reproductive harm is revised

Safe Harbor Levels

- Cancer: no significant risk level (NSRL)
- Reproductive harm: maximum allowable dose level (MADL)
- Based on levels of exposure, not concentration

Safe Harbor Levels (cont.)

- OEHHA established 300 safe harbor levels
 - <http://oehha.ca.gov/media/downloads/proposition-65/report/p65safeharborlevels.pdf>
 - No safe harbor level?
 - Must include warning unless it can be proven exposure level will not pose significant risk of causing cancer or reproductive harm

Penalties

- Civil penalties up to \$2,500 per day for each violation
 - Factors considered:
 - The nature and extent of the violation
 - The number of, and severity of, the violations
 - The economic effect of the penalty on the violator
 - Whether the violator took good-faith measures to comply with this chapter at the time these measures were taken
 - The willfulness of the violator's misconduct
 - The deterrent effect that the imposition of the penalty would have, both on the violator and the regulated community as a whole
 - Any other factor that justice may require
 - Injunctive relief
 - Attorneys' fees and costs

Regulations in August 2018

- OEHHA amended the Prop 65 regulations
 - Effective August 30, 2018
 - Warning regulations applicable for Food and Alcohol:
 - 27 CCR § 25607.1-.2 - food exposure warnings
 - 27 CCR § 25607.3-.4 - alcoholic beverage exposure warnings

Amended Regulations (cont.)

- Product warning changes
 - Standards for text size (no smaller than 6 point)
 - Requires name of chemical to be included in warning, unless label uses the permitted short form warning
 - Label must include following symbol: 
 - Internet purchases: warnings must appear on product display page
 - Catalogs: warnings must be clearly associated with product being purchased

Amended Regulations (cont.)

- Food products warning changes
 - On-product warning label must be set off from other surrounding information in an enclosed box
 - Warning must include name of chemical(s)
 - Internet purchases: warnings must appear on product display page
 - Catalogs: warnings must be clearly associated with product being purchased

Amended Regulations (cont.)

- Sample consumer product warning labels (short form)
 - ⚠ **WARNING:** Cancer—www.P65Warnings.ca.gov
 - ⚠ **WARNING:** Reproductive Harm—www.P65Warnings.ca.gov
 - ⚠ **WARNING:** Cancer and Reproductive Harm—www.P65Warnings.ca.gov
- Short form warnings not permitted for food or alcohol!!!

Amended Regulations (cont.)

- Sample food product warning label (including dietary supplements)
 - **WARNING:** Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov/food.
 - **WARNING:** Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.
 - **WARNING:** Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.
 - **WARNING:** Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.
- Warning must be set off in a box apart from other surrounding information on the food product.

Amended Regulations (cont.)

- Sample alcoholic beverage warning label
 - **WARNING:** Drinking distilled spirits, beer, coolers, wine and other alcoholic beverages may increase cancer risk, and, during pregnancy, can cause birth defects. For more information go to www.P65Warnings.ca.gov/alcohol.
- Warning must be no smaller than the largest type size used for other consumer information on the product. In no case can the type size be smaller than 8 point.
- The warning should be placed on the shipping container or delivery package
- Retailers and restaurants have their own requirements to provide a Prop 65 warning

New Prop 65 Notice Provision

- Can provide notice to a "retail seller" that places responsibility on the retail seller to provide a Prop 65 warning to the end-user, including internet and catalog sales
- Notice must include the following elements to be effective:
 - (1) States that the product may result in an exposure to one or more listed chemicals
 - (2) Includes the exact name or description of the product or specific identifying information for the product such as a Universal Product Code or other identifying designation
 - (3) Includes all necessary warning materials such as labels, labeling, shelf signs or tags, and warning language for products sold on the internet
 - (4) Has been sent to the authorized agent for the retail seller, and the manufacturer, producer, packager, importer, supplier or distributor has obtained confirmation electronically or in writing of receipt of the notice
- Notice must be renewed on February 28, 2019 and annually thereafter

Questions?



Thank You!



Managing Risk in the Food & Beverage Industry

Seminar & Panel Discussion

Wednesday, December 5, 2018 · 7:30am - 11:30am