



HOT TOPICS IN FOOD AND BEVERAGE LAW

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FOOD AND BEVERAGE INTRODUCTION

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Food and Beverage in Wisconsin

- Wisconsin agriculture generates more than \$88.3 billion in economic activity
- Wisconsin has nearly 1,700 food, beverage and ingredient manufacturers (more than 253 in Milwaukee)
- Milwaukee has 2nd highest concentration of food industry talent among U.S. 50 largest metro areas
- Wisconsin ranks nationally:
 - No. 1 in (i) food manufacturing equipment and flexible packaging and (ii) cheese
 - No. 2 in (i) certified organic operations, (ii) dairy, (iii) milk production and (iv) meat processing
 - No. 5 in food manufactured products

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FDA INSPECTIONS: THE CURRENT LANDSCAPE, WHAT TO EXPECT, AND HOW TO BE READY

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FDA Under the New Administration

- President names FDA Commissioner nominee: Scott Gottlieb
- Few public comments from new administration on food safety matters
- Federal hiring freeze, effort to eliminate regulations, and possible FDA budget reduction
- Uncertain landscape for enforcement

FDA Inspections

- Authority: FDCA § 704
- Reasonableness of the inspection
 - Time, place, manner
- Reasons
 - Routine, for cause, pre-approval, compliance, criminal
- Consent is unnecessary
 - Inspection warrant
- **Frequency increased under FSMA**

Before an Inspection

- Prepare written inspection manual that contains:
 - List of members of inspection team
 - Company inspection policy
 - Affidavits
 - Photography
 - Questioning of employees
 - Trade secret/confidential information
 - Access to company records



Before an Inspection (cont.)

- Procedures for responding to arrival of inspector
 - Procedures for interacting with inspector
 - System to document entire inspection
 - Instructions for resolving issues before and after inspection
 - Miscellaneous
- Make sure your house is in order
- Mock inspections
- Self-audits

Before an Inspection (cont.)

- Investigators prepare for inspections by reviewing:
 - Company's history
 - Compliance program guidance
 - Company's registration and listing information
 - Public information
- Investigators prepare equipment, sample collection materials, preprinted seals, etc.

During the Inspection

- Greeting of inspector
 - Escort inspector to suitable area
 - Notify inspection team
 - Request that legal counsel remain "on call" to assist in answering pressing questions as they arise
- Pre-inspection conference
 - Verify credentials
 - Determine purpose of inspection
 - Notify FDA of company policies affecting inspection

During the Inspection (cont.)

- Affidavits or "statements"
 - **Do not sign**
 - Do not comment
 - Get proposed affidavit for legal counsel's review
- Photography
 - No express legal authority to do so
 - Adopt policy beforehand
 - If photos are allowed, the facility should take pictures of whatever the investigator photographs and do so from the same angle/point of view

During the Inspection (cont.)

- Questioning of employees
 - No express legal authority to do so
 - Nonmanagerial vs. managerial employees
 - Do not volunteer information
- Trade secret / confidential information
 - Designate beforehand



During the Inspection (cont.)

- Records review
 - FSMA recordkeeping requirements
 - Written food safety plan, including hazard analysis
 - Records that document preventive controls, monitoring, corrective actions and verification
 - Must be kept for two years
- Visual inspection
- Sampling/swabbing

During the Inspection (cont.)

- Inspecting the facility
 - Inspector will request tour
 - Designated personnel should accompany inspector
 - Correcting deficiencies uncovered during the inspection



During the Inspection (cont.)

- Interacting with the inspector
 - Be professional and cooperative
 - Ask questions to clarify comments or requests
 - Attempt to limit scope of inquiries
- Answering the inspectors' questions
 - Only those reasonably related to the inspection
 - Do not volunteer
 - Do not speculate
 - Be truthful

During the Inspection (cont.)

- Inspection exit interview
 - Inspector will meet with management to discuss observations
 - Inquire about when reports or analysis on samples will be provided



During the Inspection (cont.)

- Inspection exit interview
 - Form FDA-483 - inspectional observations
 - Provided to top management before completion of the inspection
 - Written notice of significant objectionable matters observed during inspection
 - Does **not** constitute final agency determination regarding compliance
 - Each "observation" should be addressed
 - Management may comment, but **no *impromptu commitments***
 - Response within 15 days is **strongly recommended** to avoid further regulatory action

After the Inspection

- Post-inspection meeting of inspection team
 - Make detailed notes of what took place
 - Compile inspection file; prepare report for management
 - Review Form FDA-483 and consider appropriate corrective actions
 - Confer with legal counsel about the response and action plan

After the Inspection (cont.)

- Establishment Inspection Report ("EIR")
 - Inspectors are required to prepare an EIR after an inspection
 - Must contain detailed descriptions of the entire inspection
 - Must identify any conditions/practices where food:
 - Consists of filthy, putrid or decomposed substance; or
 - Has been prepared, packed or held in unsanitary conditions whereby it may be contaminated with filth rendered injurious to health
- Review EIR for errors and consult legal counsel regarding what items require response/how to respond

After the Inspection (cont.)

- FDA actions following the inspection
 - EIR, Form-483 and sample test results are forwarded to a Compliance Officer at the district office
 - Based on this information, the Compliance Officer will make one of the following decisions:
 - No further action is warranted;
 - Order a re-inspection to ensure that promised corrective action has been completed and that problems have been rectified; or
 - Recommend further regulatory or legal action depending on the seriousness of the violations and regulatory history

FDA Enforcement Options

- Warning letter
- Injunction
- Administrative detention
 - Temporary measure to prevent food that the FDA has "reason to believe" is "adulterated or misbranded" from entering commerce
 - FSMA broadened the standard (rather than "credible evidence" that food presents a "threat of serious adverse health consequences or death")

FDA Enforcement Options (cont.)

- Criminal prosecution
 - Recommended when a company has demonstrated an unwillingness to correct a violation or when the violation is flagrant, intentionally committed, or involves a health hazard that the company did not try to prevent or correct
 - Peanut Corporation of America
 - Park Doctrine - Intent to violate the law does not need to be shown
 - Jenson Farms
 - Quality Egg

Conclusion

- FSMA demands increased inspection frequency, but enforcement landscape uncertain with new administration
- Involve the entire organization
- Go back to basics
- Keep good records
- Train, train, train
- Prepare for FDA inspections
- Nurture your FDA relationship
- Stay vigilant



Questions?



Thank you!

BRANDING AND TRADEMARK SELECTION CHALLENGES

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How do I secure trademark rights?

- Use in Commerce!*
- Common Law (use without formal registration)
 - First to use
 - Rights arise from use of a trademark in commerce
 - Only available in the United States, United Kingdom, Australia and Canada
 - Fraught with problems, compared to registration
 - Interstate commerce required for U.S. federal registration
- Statutory Protection (formal registration)
 - First to file
 - Rights arise only from formal registration
 - Provides key benefits in common law countries
 - Registration is required for protection in noncommon law countries

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When should I seek federal registration?

- Should I file now to preserve my future rights or should I take the wait-and-see approach?
- Will the trademark serve to distinguish my goods or services in the marketplace?
- Is the trademark in use? If not, when will it be in use? (Short term versus long term horizon.)
- Will the trademark be used for only a short period of time?
- Will the trademark be used on goods or services? (Concepts, beliefs, internal marketing concepts are not trademarks.)

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What if I don't seek federal registration?

- Common law rights are limited
- In “first to file” countries, a squatter may bar use and registration
- In “common law” countries, a third-party registration may box you in to a specific market or territory
- In the United States, incontestability is a worthy prize. The sooner you become incontestable, the better.
- An incontestable third-party registration may be impossible to overcome

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Not all trademarks are created equal

- **Inherently Distinctive Terms** - immediately enforceable if properly used and enforced
- **Descriptive Terms** - can acquire distinctiveness through exclusive and continuous use over time
- **Generic Terms** - cannot become an enforceable trademark

Good Trademarks - Inherently distinctive

- **Fanciful Trademarks** - terms that have been invented for the sole purpose of functioning as a trademark or service mark and are unknown or uncommon in the language (e.g., Pepsi, Kodak, Exxon)
- **Arbitrary Trademarks** - common words that do not suggest or describe a significant ingredient, quality or characteristic of the goods or services (e.g., Apple for computers)
- **Suggestive Trademarks** - require imagination, thought or perception to reach a conclusion as to the nature of the goods or services

Weak (bad) trademarks

- A descriptive trademark serves only to describe a feature or characteristic of the goods or services
 - APPLE PIE held merely descriptive of potpourri
- Other descriptive examples: Surnames, geographic locations and laudatory terms (great, best, etc.)
- Descriptive trademarks can become distinctive
 - Five years of exclusive and continuous use
 - Other evidence showing that the trademark has acquired distinctiveness among relevant customers
 - May be registered on the “Supplemental Register” if not distinctive yet

Clearance Search - the first step

- Goal is to identify three areas of risk:
 - **Infringement** - will your selected trademark violate the rights of an existing trademark in the particular country?
 - **Procedural** - even if the trademark does not infringe, it may not be possible to register or it may be too costly
 - **Value** - even if the trademark does not infringe, and even if we can secure a registration, it may not be enforceable or it may be diluted

Word vs. Design Trademarks

- Word Only
 - Protects words without regard to font, style or other graphic elements
 - Broadest protection
- Design
 - Protects combinations of words, graphics, colors, etc.
 - Does not provide full protection for word elements alone
 - May help create distinctiveness when words alone are weak

Specimen Requirements

- The trademark appearing on the specimen must match the “Drawing” of the trademark in the application - EXACTLY
- Once an application is filed, the drawing cannot be amended unless the amendment is nonmaterial
- Materiality is subjective



Trademark Notices

- TM and SM
 - May be used without a registration
 - May be used before or during application process
- ®
 - May only use in the United States if a trademark is formally registered
 - Other countries have different rules, or no rules

Improper use may result in loss of rights

- Using a trademark improperly can result in loss of rights
 - Descriptive or generic usage by you or others (Aspirin, Kleenex, Google, Xerox)
 - Inconsistent usage (spelling, combining with other words, etc.)
 - Incidental or infrequent use
 - Use on wrong goods or services (consider additional filings)
 - Improper (naked) licensing

Questions?



Thank you!

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CORPORATE CONCERNS: ANSWERING REOCCURRING F&B QUESTIONS

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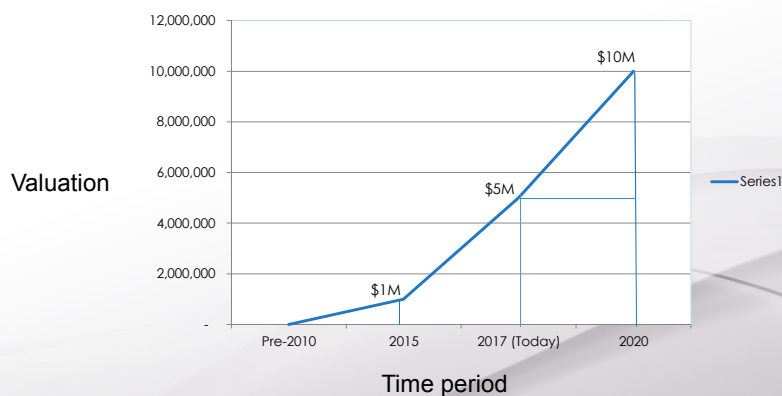
Today's Topics

1. Offering Profits Interests to Key Personnel
2. Raising Capital and this thing called a SAFE Agreement
3. Issues in Operating Agreements and/or Shareholder Agreements

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Profits Interests



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Profits Interests (cont.)

- Threshold Value
- Vesting:
 - Time Vesting
 - Performance Vesting
- Repurchase Rights
- Change of Control
- Form 83(b)

Raising Capital

- Think Exit Strategy
 - Friends and Family/Angels
 - Venture Capital
- Financial Statements
- Private Placement Memorandum

Raising Capital (cont.)

➤ SAFE Agreement

- Example: In 2013, you received an aggregate of \$500,000 from F&F/Individual Angels in exchange for 5% of the Company
- The post-money value is \$10M
- In 2017, you seek additional capital of \$1M from a more sophisticated investor (VC fund); however, the pre-money value is \$4M
- Now what?

Raising Capital (cont.)

➤ SAFE Agreement

- (1) Insist on the \$10M valuation;
- (2) Take the \$1M for 25% and leave F&F as is; or
- (3) Accept the \$1M for 25% and retroactively adjust the 2013 valuation

Operating Agreement and/or Shareholder Agreement

- Permitted Transfers
- Other Transfers (Death, Disability, Termination)
- Waterfall
- Restrictive Covenants

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