Legal Considerations

Designing a Sampling & Testing Plan

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Preface

- This presentation is for general informational purposes only. It is not intended to and does not constitute legal advice. Please contact your attorneys if you need legal advice.

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Today's Presentation

- Defining Separate Kinds of "Liability"
- FDA Authority Over Records Access
- Document Retention and Destruction
- The Limits of Privilege

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Types of “Liability”

- Liability Under the Food, Drug, and Cosmetic (FD&C) Act, as amended by the Food Safety Modernization Act (FSMA)
- Product Liability
- Other Commercial Liability/Trading Partners

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FD&C Act Liability

- FSMA section 103, Hazard analysis and risk-based preventive controls (HARPC), *implemented by* 21 C.F.R. Parts 110 and 117
- FSMA section 104, Standards for produce safety, *implemented by* 21 C.F.R. Part 112
- Failure to comply with the regulatory requirements established under FSMA is a ***prohibited act***
- Food produced in violation of the regulatory requirements may render the food ***adulterated as a matter of law*** (FD&C Act § 402(a)(4)

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Recordkeeping

- HARPC requires *verification* of implementation and effectiveness, *which may include* ***product testing*** *or* ***environmental monitoring***. 21 C.F.R. 117.165(a)
- Produce Safety Regulation requires recording "Actual values and observations obtained during monitoring." 21 C.F.R. 112.161(a)(1)(ii)
- To the extent sampling and testing are part of your verification/monitoring procedures, you are generating *required records*

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Records Access

- Ordinary FDA Authority: All required records
- Special Records Access: If consumption of or exposure to a food presents a threat of *serious adverse health consequences or death to humans or animals (SAHCoDHA)*, upon presentation of written notice, FDA can access *"all records"* regarding that food *as well as records regarding any other food that "is likely to" have been affected in a similar manner*
- Arguably reaches even non-required records

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Freedom of Information Act & Trade Secret/Business Confidential Information

- Exempt from disclosure under FOIA “Exemption 4”
- Documentation should be marked “TRADE SECRET/BUSINESS CONFIDENTIAL”
- Registered facilities and farms should request “pre-release review” for any records copied by FDA
- Exemption does *not* apply to evidence presented by FDA in court actions

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Product Liability

- Scope of Discovery: All relevant information and information that *may lead to* relevant information
- Disclosure of discovery is commonly limited by non-disclosure orders issued by the presiding court
- Evidence at trial becomes public record
- Preventing disclosure of damaging information is often a significant factor favoring settlement – either with private litigants or FDA

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Other Commercial Liability/Trading Partners

- Same considerations as in Product Liability context
- If Trading Partner desires access to testing records, Non-Disclosure Agreements should be considered
- Suppliers should ensure that customers are obligated to timely disclose any testing performed for or by the customer
- Suppliers should ensure that customers are obligated to timely advise of any regulatory sampling

Document Retention & Destruction

- HARPC Requirement: 2 years after document is prepared
  - Records that relate to general adequacy or equipment or processes, “including scientific studies and evaluations”: 2 years after use is discontinued. 21 C.F.R. 117.315(a), (b)
- Produce Safety Rule: 2 years after the record is created.
  - Records that relate to general adequacy of equipment or processes or “records that relate to the analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations”: 2 years after the equipment, processes or records related to analysis, sampling, or action plans is discontinued. 21 C.F.R. 112.164

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The Limits of Privilege

- Privilege Rules (Attorney-Client, Doctor-Patient, Priest-Penitent) are Rules of Evidence, *i.e.*, what can and cannot be presented in court
- Privilege
  - belongs to the client (except for the exceptions)
  - Privilege is easily lost by “waiver” (non-confidential treatment)
  - Privilege cannot extend to a required record
- There are slight variations in State laws and court rulings

What Does Attorney-Client Privilege Protect?

- Actual or potential client communicates with a lawyer
- Lawyer is acting in their professional capacity (not as a business advisor)
- Client intends *and acts* to keep the communication(s) confidential
- Lawyer has separate obligation to keep communication confidential, absent established exceptions

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What *Doesn't* A-C Privilege Protect?

- Statements made in furtherance of a crime or scheme to defraud
- Any information once it is treated in a non-confidential manner
  - Any contact outside the corporation would waive privilege
  - Once waived, the privilege cannot be revived
- Anything you just "sent to the lawyer" but did not otherwise treat as a communication between a lawyer and a client

How Does this Work in a Corporate Setting?

- Privileged material should be confined to the corporation's "control group"
  - senior management and
  - a limited number of others have a "need to know" the information in order to carry out their job functions
- Every act of distribution of the communication increases the chances that the privilege will be accidently waived

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Questions?

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