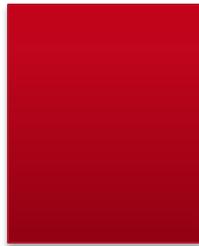


# MICHAEL BEST

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*Outside Resources to Consider During a Food Product Recall*

WAFP Food Safety Industry Issues  
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## Overview

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- Lifecycle of a Food Recall
- The Importance of Counsel
- Steps / Points for Engaging Experts / Services

## Lifecycle of a Food Product Recall

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- Establish whether a recall is necessary
- Identify the product to be recalled
- Drafting and disseminating the recall communication
- Product recall logistics
- Reporting to regulatory authorities
- Closing out the recall

## Is Recall Necessary?

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- Regulatory counsel
  - Used to establish the legal responsibilities
- Laboratories
  - Testing to establish the organism / contamination
  - Cross-check results from in house testing
- Toxicologists, Physicians, Epidemiologists
  - Used to establish the health hazard

## Identification of Product

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- Laboratories
  - Testing to identify suspect lots
- Manufacturing Consultant
  - Help with root cause analysis
  - Use information management systems to obtain relevant information

## Recall Communication

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- Supply Chain Consultant
  - Helps to establish the appropriate level for the recall (distributor, retail, consumer)
  - Identify, locate and track affected product
- PR Firm
  - Craft the language of the recall communications (provide appropriate level of detail and give comfort to consumers, distributors and retailers)
- Regulatory Counsel
  - Legal language that needs to be included (regulator required language, product liability concerns)

## Recall Logistics

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- Laboratories / Toxicologists
  - Establish whether product can be reprocessed
- Supply Chain Consultant
  - Help to determine the best method to effect the recall (who retrieves the product, return to manufacturer or destroy on site)
- Call Centers
  - Handle consumer questions, reports of illness
- Other recall service providers
  - Notification services (notice design & execution)
  - Assist with recordkeeping and recall logistics
  - Rebates, reimbursements, product retrieval, replacement product

## Regulatory Reporting

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- Regulatory Counsel
  - May serve as the principal contact with regulatory authorities (FDA, USDA, FSIS, state agencies, etc.)
  - Help to fashion company's written correspondence with regulators
- Toxicologists, Physicians, Epidemiologists, Microbiologists
  - Defend health hazard analysis with regulators
- Same team to assist with follow-up, mitigation, process/facility/management changes, etc. ("lessons learned")
- Liability & insurance coverage considerations
  - Product recall insurance, third-party costs, etc.

## Closing out the Recall

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- Regulatory counsel to coordinate with regulatory agencies to confirm termination of the recall
  - Confirm timely and effective recall
- Address/prepare for enforcement issues, if any

## Importance of Legal Counsel

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- P R I V I L E G E
  - Attorney-Client Privilege
    - Applies to both inside and outside counsel and to corporations as well as individuals
  - Work Product Doctrine

## Wisconsin's Attorney-Client Privilege

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- Wis. Stat. § 905.03
  - Applies to confidential communications between the client, the lawyer, and, if applicable, the lawyer's representative
  - "Confidential communication"
    - Communication not intended to be disclosed to 3<sup>rd</sup> persons other than those to whom disclosure is in furtherance of the rendition of professional legal services to the client
  - "Lawyer's representative"
    - One employed to assist the lawyer in the rendition of professional services.
- Limitations
- Absolute privilege; gives way when the client voluntarily waives

## Work Product Privilege

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- Applies to work “prepared in anticipation of litigation or for trial by or for another party or by or for that other party’s representative.”
  - Information the lawyer has assembled and the mental impressions, legal theories, strategies pursued derived from interviews, statements, memoranda, correspondence, briefs, legal and factual research, mental impressions, personal beliefs and strategies of others.
- Can include materials, information, mental impressions and strategies of others that attorneys assimilate as part of their own work product.
  - Before a document/item can be classified as attorney work product, must have been obtained at the attorney’s direction and in anticipation of litigation.

## Privilege Issues

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- In-house counsel vs. outside counsel
  - Business advice vs. Legal advice
    - Clear designation that protected communications are sent to counsel in his/her capacity as a *legal* adviser
- Protection of communications, not underlying facts
- Disclosure to 3<sup>rd</sup> parties
  - Attorney-client privilege waived when the client voluntarily discloses an otherwise confidential communication to 3<sup>rd</sup> party
    - *Except* if 3<sup>rd</sup> party is an agent assisting the lawyer in rendering professional legal services
  - Work-Product Privilege extends to work prepared in anticipation of litigation by or for another party or by or for that other party's representative

## Steps / Points for Engaging Experts / Services

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- Outside consultant engaged by counsel
- Engagement agreements with all 3<sup>rd</sup> party agents preserving both the attorney-client and work product privileges
  - Indicate 3<sup>rd</sup> party agents retained for purpose of assisting lawyer(s) in providing professional legal services
  - All communications are considered highly confidential
  - All work to be performed at the direction of counsel

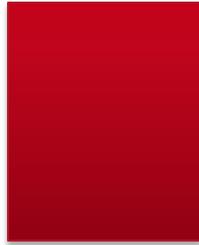
## Questions?

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