RECALLS

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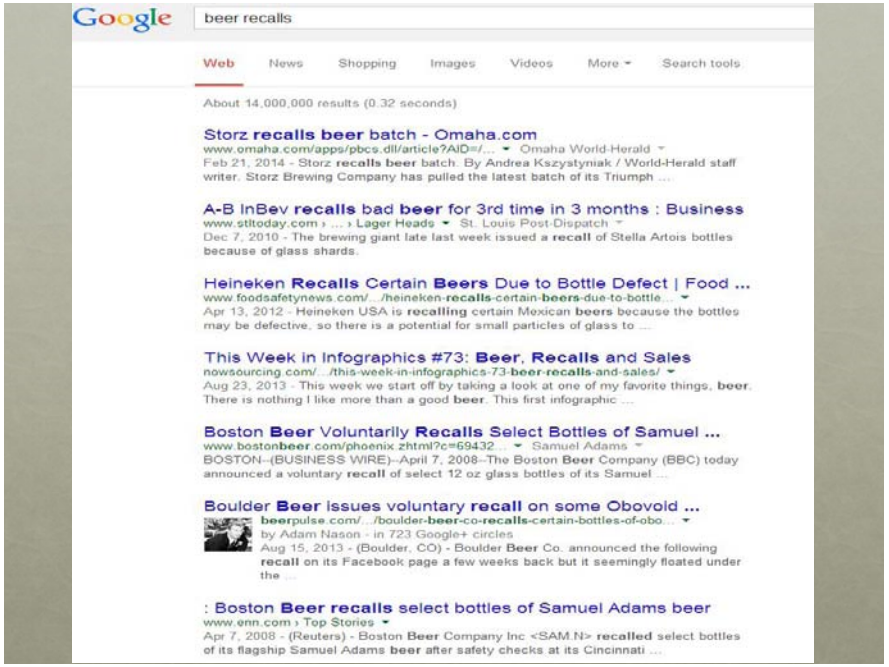


Boulder Beer issues voluntary recall on some Obovoid bottles, urges safety precautions

Heineken Recalls Certain Beers Due to Bottle Defect
BY NEWS DESK | APRIL 13, 2012

A-B InBev recalls bad beer for 3rd time in 3 months

Anheuser-Busch Recalls Beer After Man Is Poisoned
November 18, 1995 | STEVE RYFLE | SPECIAL TO THE TIMES

Carta Blanca, Dos Equis Ambar, and Indio Beer Recalls

Beer Man
Odell Brewing recalls its latest high-end beer, Hiveranno, because of carbonation problems
By Jonathan Shikes Wed., Jul. 6 2011 at 4:06 PM 1 Comment

U.S. BUSINESS NEWS
Boston Beer Recalls Some Bottles Of Sam Adams Over Glass Concerns

WHAT IS A RECALL?

The process a brewery must take to remove unsafe or violative product from the market. The goal is:

1. Stop delivery and sale of product in question;
2. Inform the appropriate regulatory agencies; and
3. Proper and timely removal from market of product in question.

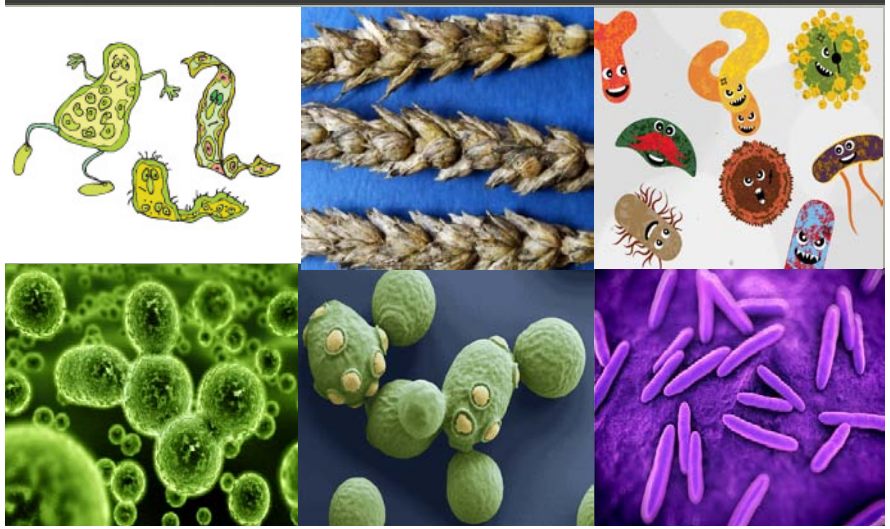
REASONS

- ADULTERATION
  - PHYSICAL
  - CHEMICAL
  - BIOLOGICAL
- MISBRANDING

ADULTERATION: PHYSICAL

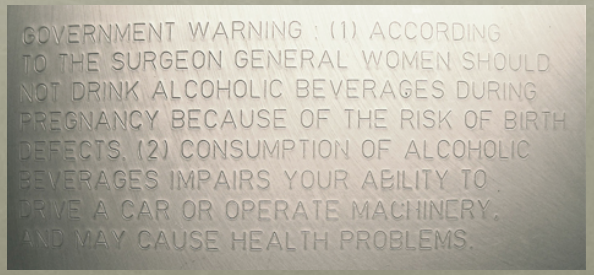
ADULTERATION: CHEMICAL

ADULTERATION: BIOLOGICAL



MISBRANDING

- False, misleading or missing information on labels
- Undeclared allergens – mandatory for FDA regulated labels



WHAT IS A RECALL ACTION PLAN?

A carefully constructed, tested and evaluated plan to ensure efficient removal of products from the market.

RECALL PROCEDURES

1) IDENTIFY the concern
2) EVALUATE the hazard and notify management
3) ASSEMBLE the recall team
4) NOTIFY your applicable regulatory agencies
5) IDENTIFY all products to be recalled
6) SEGREGATE affected products that are in your control
7) PREPARE a distribution list

RECALL PROCEDURES

7) NEWS RELEASE (if necessary)
8) NOTIFY all customers what to do with the recall products (wholesalers, retailers and consumers)
9) CONTROL recalled products and decide what to do with them
10) DISPOSE/DESTROY recalled products
11) FIX the cause of the recall

IDENTIFY CONCERN

- Direct from consumer
- Social Media
- Raw Material Supplier
- Regulatory Notification: FDA, TTB or other government agency
- Internal observations or lab results
- Field sales observations
- Wholesaler or retail observations

WHAT TO GATHER:

- Name/address/contact information
- Problem Details
- Product Details
- Retail Details
- How product was stored and handled
- Detailed illness inquiry
- Complaint referred to anyone else? (FDA, TTB, public health agency)

RECALL TEAM

- Recall Coordinator
- Distribution Coordinator
- Sales Coordinator
- Media Coordinator
- Operations Coordinator
- Purchasing Coordinator
- Quality Assurance/Technical Coordinator
- Accounting/Inventory Reports Coordinator
- Regulatory Affairs Coordinator

RECALL COORDINATOR

- Assure the documentation of all recall decisions and actions in a master recall file.
- Initiate the formation of the recall committee.
- Activate various components within the company for priority assistance.
- Make recall decisions on behalf of company
- Manage and coordinate the implementation of the company's product recall.
- Keep management informed at all stages of the recall.

RECALL TEAM AND KEY PERSONNEL CONTACT INFORMATION

All phone and fax numbers, email address, and alternate 24/7 information of all committee members, their alternates, labs, and "outside" key personnel.

This list should be confirmed and updated as often as necessary to assure accuracy.

WHO TO CONTACT?

- TTB Assistant Director for the Market Compliance Office
- FDA Seattle District Recall Coordinator (AK, ID, MT, OR, WA)
- Alcohol Beverage Control Boards
- Departments of Health
- Other equivalent organizations

TTB AND FDA MOU

Department of the Treasury
TTB

"VOLUNTARY" RECALLS

TTB **does not have the authority** to enforce a voluntary recall.

TTB will investigate incident which may include an **audit** of the industry member to examine financial records and other documentation relating to the manufacture, removal, or sale of the recalled product.

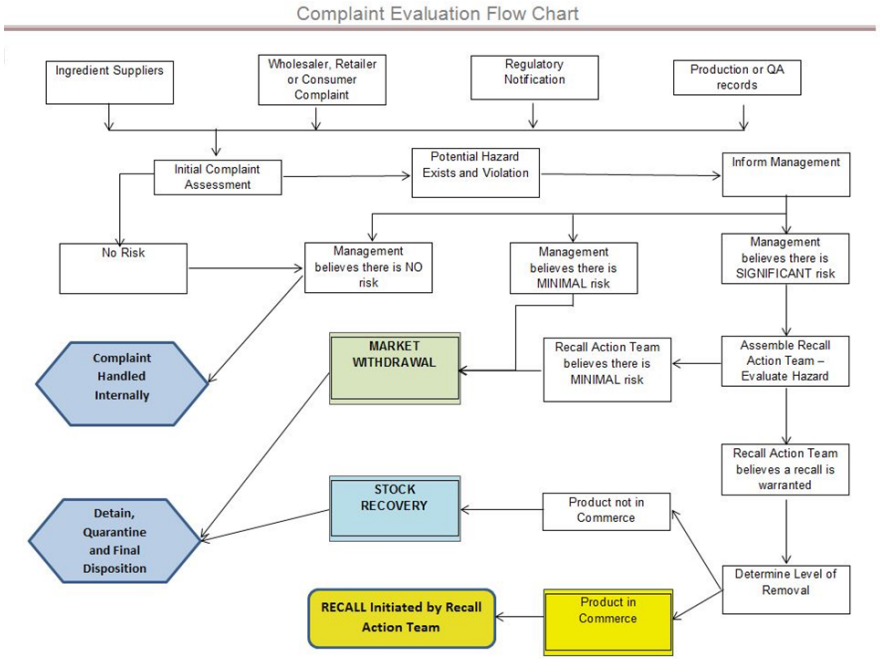
FDA **has authority** to enforce a recall under §206 of Food Safety and Modernization Act

LESS THAN 7% WINES & CIDERS AND FDA "BEERS"

- The FDA is responsible for taking the lead on recalls pertaining to these products.
- The TTB should be notified so they are aware and know you are working with the FDA.

EVALUATE COMPLAINT HAZARD

- Conduct a preliminary Hazard Evaluation
- Determine degree of seriousness of the product
- Determine possible causes (sole, major, contributing factor, no role)
- Determine if a preliminary health hazard may or may not exist
- If health hazard may exist, place any product in inventory on QA HOLD immediately
- Collect all reported health information/adverse reactions
- Trace all lots in distribution
- Notify recall coordinator



CLASSIFICATION

- Class I: Imminent Health Hazard
- Class II: Remote Possibility of Serious Health Problem
- Class III: Unlikely to Cause Adverse Health Consequences
- Market Withdrawal
- Stock Recovery

CLASS I: IMMINENT HEALTH HAZARD

A health hazard where there is a reasonable probability that the use of or exposure to the product will cause serious, adverse health consequences or death. This shall be treated as an emergency situation involving 100% removal of product from the market. The hazard may be chemical, physical or biological.

Examples: A food found to contain *botulinal* toxin or a food with undeclared allergens.

CLASS II: REMOTE POSSIBILITY OF SERIOUS HEALTH PROBLEM

A health hazard where use of or exposure may cause temporary or medically reversible adverse health consequences or where there is a remote probability that the use of the product will cause serious adverse health consequences.

Example: bacterial contamination, undeclared ingredients or contamination such as metal or glass fragments.

CLASS III: UNLIKELY TO CAUSE ADVERSE HEALTH CONSEQUENCES

Situation where the use of the product will not cause adverse health consequences, but the product does not meet quality specifications or violates FDA/TTB labeling or manufacturing laws. Products recalled because of misbranding not involving a health hazard fall into this category.

Example: A minor container defect, like exterior plastic delaminating, off flavor or color, or missing government warning on label.

MARKET WITHDRAWAL

A voluntary action to remove or correct product *in distribution* that involves a minor violation that would not warrant legal action by the FDA/TTB and does not constitute a health hazard as defined as a recall. The FDA may or may not be involved. Company would remove the product from the market or correct the violation.

Example: A product removed from the market because of the wrong product was shipped, labels have minor violations, such as improper net weight, or as part of a normal stock rotation.

STOCK RECOVERY

When a company removes or corrects a product that has not been marketed or that has not left the direct control of the company. *No portion of the lot has been released for sale or use.* FDA is usually not involved with stock recoveries.

Example: A quality assurance hold is considered a stock recovery when it does not meet organoleptic standards as determined by the company.

NOTIFICATION

- SHIPPING COMPANY
- WHOLESALERS
- RETAILERS
- CONSUMERS
- GOVERNMENT AGENCIES
- PRESS AND SOCIAL MEDIA (IF NECESSARY)

FDA REPORTABLE FOOD REGISTRY

You must file a report through the RFR electronic portal when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

www.safetyreporting.hhs.gov

- ✓Must report as soon as practicable, but within 24 hours after it is determined that an article of food is a reportable food
- ✓Must submit certain data elements report
- ✓Must investigate the cause of the adulteration
- ✓May be required to provide notification to immediate previous sources and immediate subsequent recipients of the reportable food after consultation with FDA
- ✓Must provide amended reports
- ✓Must consult with FDA to follow up
- ✓Must maintain records related to each report for 2 years

MEDIA STRATEGY

Need a written statement released to the news media and/or other groups or organizations that disseminate recall details to the public.

NEWS RELEASE

- HEADER
- FIRM CONTACT INFORMATION & DATE
- STATEMENT OF RECALL
- DETAILED PRODUCT INFORMATION
- STATEMENT OF ILLNESS
- CONSUMER DIRECTIVE
- REGULATORY NOTIFICATION
- FIRM CONTACT INFORMATION

RECALL EFFECTIVENESS

- Verify that all customers have stopped the distribution of the affected products
- Ensure all recalled products have been returned to the brewery or distributors' control or other designated area as instructed in the recall notification
- Ensure all product is destroyed

RECALL TERMINATION

1) Company, TTB or FDA determines that *all reasonable efforts have been made* to remove or correct the product in accordance with the recall strategy and;

2) When it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product.

If FDA is involved, written notification will be provided by the respective FDA district office.

DEBRIEF AND REVIEW PROCESS

- Effectiveness
- Recall Status Reports
- Root Cause of Problem that Resulted in Recall
- Corrective Actions

PREPARE FOR LEGAL EVENTUALITIES

- Product Liability Lawsuits:

  Strict Liability or Negligence; Punitive Damages; Class Action

- Civil or Criminal Cases

MOCK RECALLS

- Test company's ability to recall products without actually recalling them.
- Are strongly suggested and should be tested on an annual basis.
- Goal:
  1) Identify every affected lot;
  2) know exactly where it is at any point in the process;
  3) know who to contact to bring it back **within 4 hours.**

MOCK RECALL

- Test both product-tracking and raw material-tracking systems.
- Results of the practice must show that a brewery is able to handle a recall situation (a 95-100% efficiency rating).
- If deficiencies are identified, correct the problems and retest the program with another mock recall.
- Retain records as verification

Company XYZ	MOCK RECALL FORM	Form F-F05 Page 1 of 2
Issued on: Issued by:	Version No: 1 Supersedes:	Revised:

1. DETAILS

Date: _____

Mock Recall Start Time: a.m. / p.m. _____

Recall Coordinator/Alternative: _____

Product Name: _____

Production Date: _____

Best Before Date: _____

Lot Code Number: _____

Recall Classification: Units (i.e. Point of purchase boxes, cases) _____

Production/Purchase Volume _____

Remaining Stock Volume _____

Distributed Volume _____

Completion Time: _____ **a.m./p.m.**

****Note: Mock Recall must be completed within four hours of start time.**

2. STATUS OF PRODUCT CHOSEN

A. Amount originally produced or supplied: _____

B. Amount in transit _____

C. Amount held by distributors _____

D. Amount held by retail locations _____

E. Amount held by individual consumers (include sales, samples, donations). _____

F. Total unaccounted for _____

% Mock Recall Effectiveness:

RESOURCES

- FDA's Regulatory procedures Manual (Chapter 7): http://www.fda.gov
- TTB Industry Circular 2010-6: http://www.ttb.gov

DEPARTMENT OF THE TREASURY
Alcohol and Tobacco Tax and Trade Bureau

Industry Circular
Number: 2010-6
Date: September 10, 2010