U.S. FOOD & DRUG ADMINISTRATION

Managing Recalls for Dairy

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Regulatory RoundUP
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Outline

- Voluntary Recalls
- Recall Process
- Roles and Responsibilities
- 2018 Recall Data
- Recent Recall Process Improvements

Voluntary Recalls

21 CFR Part 7, Subpart C: Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibility

- Guidance on development of recall strategy (depth, public warning, effectiveness checks)
- Guidance on recall communications with consignees
- Who to contact at FDA and what information to provide

Definitions from 21 CFR Part 7

- Recall - a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery.
- Correction - repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

Definitions from 21 CFR Part 7

- Market Withdrawal - a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
- Stock Recovery - a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

Definitions from 21 CFR Part 7

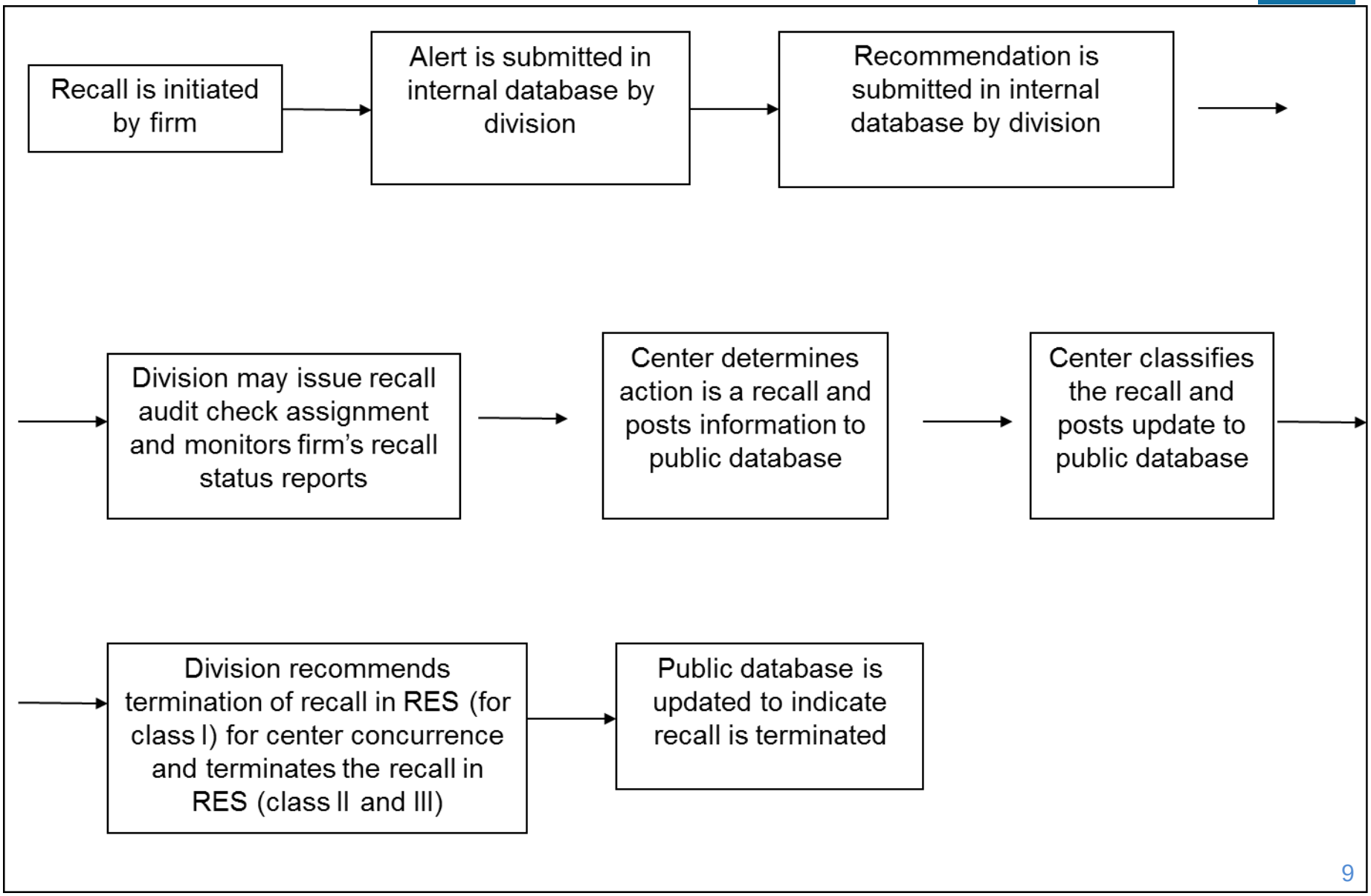
- Classification: Numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

Definitions from 21 CFR Part 7

- Class I - 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.
- Class II - 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 - a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

FDA Voluntary Recall Process

- Recall is reported by firm to FDA local division office
- Division Recall Coordinator submits alert and recommendation to center for recall to be classified, and submits any documentation needed for classification
- Division is responsible for monitoring the effectiveness of the recall throughout the process, including reviewing firm's recall status reports and assigning FDA recall audit checks
- Center determines if the action meets the definition of a recall and if it does, classifies the recalled products (I, II, or III)
- Once FDA (district for class II/III, center for class I) determines that all reasonable efforts have been made to remove or correct the product and it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made, the recall can be terminated


Recall is initiated by firm
Alert is submitted in internal database by division
Recommendation is submitted in internal database by division
Division may issue recall audit check assignment and monitors firm's recall status reports
Center determines action is a recall and posts information to public database
Center classifies the recall and posts update to public database
Division recommends termination of recall in RES (for class I) for center concurrence and terminates the recall in RES (class II and III)
Public database is updated to indicate recall is terminated

ORA Division Office Role

- FDA division offices ("local" FDA office) as the contact points for industry's reporting of voluntary recalls
- Receive notification of all voluntary recalls from regulated industry in their division (by commodity and geographical area)
- Provides guidance to recalling firm
- Reviews draft press releases and recall notices
- Assigns recall audit checks (RAC)
- Monitors recall to completion and termination

ORA/DE's Role in Recall Operations

- Oversees FDA-wide recall policy and procedures
- Cutting across all regulated commodities
- Consult to IT systems such as the Recall Enterprise System (RES)
- Provide input to recall strategy, communications and press releases
- Post recall announcements to FDA.gov

Center's Role in Recall Operations

- Determines if firm's action meets definition of recall
- Conducts health hazard evaluation
- Classifies recall I, II, III, or market withdrawal
- Comments on recall strategy, especially related to risk
- Provide input to communications and press releases
- Assigns recall number

FDA Recall Information

- FDA has mandatory authority for food recalls (since 2011), but relies primarily on voluntary recalls
  - Mandatory Recalls
    - Initiated three times
    - Twice companies voluntarily recalled
    - March/April 2018 – FDA issued a final mandatory recall order
  - Voluntary Recalls (FY18)
    - 586 food recall events
    - 195 Class I food recall events

Recent Process Improvement Efforts: Policy

FDA led an effort to improve recall processing and oversight over the last two years. Policy steps included:

- Guidance: Publication and Notification of Recalls (February 2019)
  - Clarifying when FDA and firms should issue public warnings and recommends their content and distribution
  - Establishing earlier public notification by publishing recall notices where classification is pending
- Guidance: Questions and Answers Regarding Mandatory Food Recalls

- Draft Guidance: Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls (January 2018) (describing situations where we will list retail information for recalled food)

- Draft Guidance: Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C (April 2019) (describes what a firm should do to be “recall ready”)

Recent Process Improvement Efforts: Operations

FDA led an effort to improve recall processing and oversight over the last two years.

Operational steps included:

- Formed a group of senior leaders to assure prompt investigation and action on emerging hazards (SCORE)
- Revised FDA procedures to clarify if, when, and how to recommend recall or ceasing production (See RPM 7-5-1, Firm Initiated Recalls)
- Revised RPM 7-5-3 (Mandated and Ordered Recalls)
- Added Attachment J to the RPM (Mandatory Recall Authority for Foods)
- Revised FDA procedures in the RPM and the Enforcement Report to include recalls that are not yet classified but that have been determined to meet the definition of a recall (See RPM 7-6-2)

Recent Process Improvement Efforts: Operations

Additional operational steps included:

- Revised subchapter 7.2 of the Investigations Operations Manual (IOM) to direct field staff to conduct follow-up recall activities including inspecting firms that have not provided Attachment B information necessary for FDA to recommend and classify the recall
- Revised subchapter 7.3 of the IOM to direct field staff to challenge the distribution and consignee lists provided by the recalling firm when they don't include the specific recalled lot
- Several improvements have been made to the Recall Enterprise System to increase surveillance on recall audit check timeframes and assignment tracking.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