FDA U.S. FOOD & DRUG ADMINISTRATION

Recalls

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PROGRAM ALIGNMENT

On May 15, 2017, FDA switched from geographical to program-based system.

- Office of Medical Device and Radiological Health Operations
- Office of Pharmaceutical Quality Operations
- Office of Human and Animal Food Operations
- Office of Biological Products Operations
- Office of Tobacco Operations

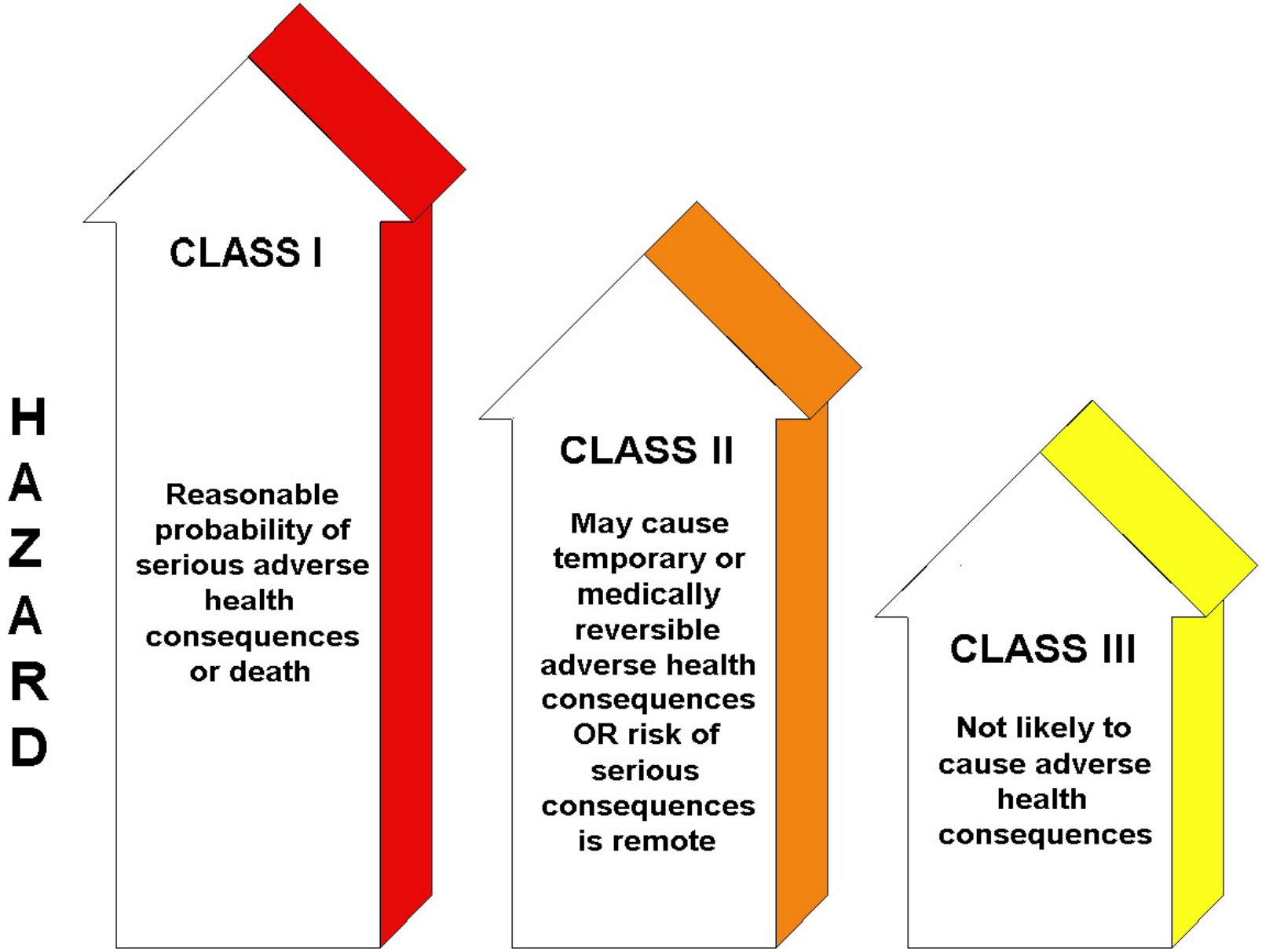
ORA Recall Coordinators | FDA

21 CFR Part 7, Enforcement Policy:

- "...provides guidelines for manufacturers and distributors to follow with respect to their voluntary removal or correction of a marketed violative products."

DEFINITION – RECALL

- Firm's removal or correction of marketed product that the FDA considers to be in violation of the law it administers and against which the agency would initiate legal action, e.g., seizure.
- Does not include a market withdrawal.
- 21 CFR Part 7.3(g)


HAZARD
CLASS I
Reasonable probability of serious adverse health consequences or death
CLASS II
May cause temporary or medically reversible adverse health consequences OR risk of serious consequences is remote
CLASS III
Not likely to cause adverse health consequences

WHAT DO YOU DO

- Call or email local FDA Division Recall Coordinator
- Discuss recall with recall coordinator to determine probable class of recall. Keep in mind that the Center makes the final determination recall classification.

CLASS I RECALLS

- Press Release: Industry Guidance For Recalls | FDA
- File an RFR (Reportable Food Registry): Reportable Food Registry for Industry | FDA
- Immediate notification/cease distribution
- Notification to user/consumer level
- Include sub-distribution notification
- 100% effectiveness checks
- Monthly Status Reports
- FDA Enforcement Report

CLASS I RECALLS

- Pathogens in ready-to-eat food: Salmonella, Listeria monocytogenes, E. coli O157:H7, botulism
- Allergens: milk, eggs, peanuts, tree nuts, crustacea, fish, soy, wheat
- High levels of sulfites
- High levels of heavy metals
- Choking hazards for susceptible populations

CLASS II RECALLS

- Press release might be recommended
- Immediate notification
- Notification to user/consumer level
- Include sub-distribution notification
- Monthly Status Reports
- FDA Enforcement Report

CLASS II RECALLS

- Foreign objects that pose a physical hazard
- Undeclared allergens with mitigating factors
- Sulfites

CLASS III RECALLS

- Immediate notification
- Notification to wholesale/retail level
- Monthly Status Reports
- FDA Enforcement Report

CLASS III RECALLS

- Filth in foods
- Minor labeling error
- Sulfite levels below 3.7mg/serving
- Food spoilage caused by mold/yeast
- Short fill weight
- Low levels of pesticide residue

TYPES OF RECALLS

- FIRM INITIATED: initiated by a firm independently and under any circumstances to remove or correct a distributed product.
- 'FDA INITIATED': Initiated by a firm when informed by the FDA that the product in question violates the law, but the agency has not specifically requested a recall (not a legal term, but an internal term).
- 21 CFR 7.46

MARKET WITHDRAWAL

- A marketed product
- Product has been in distribution channels
- A minor/no violation of FD&C Act
- Is NOT subject to legal action by FDA

POP QUIZ

You are notified by ABC Cookie Company that they must initiate a recall. They state that the product is labeled ABC Rich Chocolate Chip Cookies, but it contains their ABC Chocolate Chip Peanut Butter Cookies which causes the undeclared allergen of peanuts. What is the potential classification?

a. Class I
b. Class II
c. Class III
d. Market Withdrawal

HOW WE BECOME AWARE

- FDA inspections
- Consumer complaints
- The firm, repacker, distributor, contract manufacturer
- Competition
- Reviews from other divisions
- Other Regulatory Agencies-CPSC, CDC, State Health Dept/Medical Boards, FTC, OCI.
- Foreign (Country) agreements
- FDA Surveillance Samples

PRESS RELEASE

- To alert the public that the recalled product presents a serious hazard to health.
- Reserved for urgent situations
- Press release through general news media, and/or the specialized news media, or to specific segments of the population.

PRESS RELEASE

FOR IMMEDIATE RELEASE **DATE**
COMPANY CONTACT AND PHONE NUMBER

FOOD CO. ISSUES ALLERGY ALERT ON UNDECLARED **(ALLERGEN)** IN **PRODUCT**

Company Name of **City, State** is recalling **Quantity and/or type of Product,** because it may contain undeclared **specific type of allergen**. People who have an allergy or severe sensitivity to **specific type of allergen (e.g., peanuts, tree nuts {chestnuts, brazil nuts, walnuts, hazelnuts, pecans, pine nuts, cashews}, eggs, and sulfites)** run the risk of serious or life-threatening allergic reaction if they consume these products.

Product was distributed **Listing of the states and areas where the product was distributed** and how it reached consumers (e.g., through retail stores, mail order, direct delivery).

Specific information on how the product can be identified (e.g., type of container [plastic/glass/metal] size or appearance of product, product brand name, flavor, codes, expiration dates, etc.).

Status of the number of and types of related illnesses that have been CONFIRMED to date (e.g., "No illnesses have been reported to date.")

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description -- "the recall was initiated after it was discovered that product containing (the allergen) was distributed in packaging that did not reveal the presence of (the allergen). Subsequent investigation indicates the problem was caused by a temporary breakdown in the company's production and packaging processes."

Information on what consumers should do with the product and where they can get additional information (e.g., "consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.)

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PRESS RELEASE: DESCRIPTIVE TITLE

FOOD CO. ISSUES ALLERGY ALERT ON UNDECLARED **(ALLERGEN)** IN **PRODUCT**

PRESS RELEASE: PRODUCT AND HEALTH HAZARD STATEMENT

Company Name of **City, State** is recalling **Quantity and/or type of Product,** because it may contain undeclared **specific type of allergen**. People who have an allergy or severe sensitivity to **specific type of allergen (e.g., peanuts, tree nuts {chestnuts, brazil nuts, walnuts, hazelnuts, pecans, pine nuts, cashews}, eggs, and sulfites)** run the risk of serious or life-threatening allergic reaction if they consume these products.

PRESS RELEASE: DISTRIBUTION DETAILS

Product was distributed **Listing of the states and areas where the product was distributed** and how it reached consumers (e.g., through retail stores, mail order, direct delivery).

PRESS RELEASE: PRODUCT IDENTIFICATION

Specific information on how the product can be identified (e.g., type of container [plastic/glass/metal] size or appearance of product, product brand name, flavor, codes, expiration dates, etc.).

PRESS RELEASE: STATUS OF ILLNESSES

Status of the number of and types of related illnesses that have been CONFIRMED to date (e.g., "No illnesses have been reported to date.")

PRESS RELEASE: HOW IT WAS DISCOVERED

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description -- "the recall was initiated after it was discovered that product containing (the allergen) was distributed in packaging that did not reveal the presence of (the allergen). Subsequent investigation indicates the problem was caused by a temporary breakdown in the company's production and packaging processes."

PRESS RELEASE: CONSUMER INSTRUCTIONS AND CONTACT INFORMATION

Information on what consumers should do with the product and where they can get additional information (e.g., "consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.)

POP QUIZ

What should a recall press release include?

a. Descriptive title
b. Product and health hazard statement
c. Distribution details
d. Product identification
e. Status of illnesses
f. How it was discovered
g. Consumer instructions
h. All of the above

ATTACHMENT B

- Product Description, Trade Name and Product Usage (including labeling)
- Code Information
- Recalling Firm/Manufacturer/Firm Responsible for Violation
- Complete Reason for Recall:
  Include any analytical findings/sample results/inspectional evidence
- Root cause information
- Any injuries or illnesses connected to the recalled product.
- Volume of product in commerce:
  Quantities manufactured and distributed, and dates.
- Expected life/Shelf life
- Distribution Information
- Firm's Recall Strategy
- Firm Contact Information
- Most Responsible Person
- Recall Contact
- Public Contact
- District Audit Strategy:
- Effectiveness Level

EFFECTIVENESS CHECKS

- Conducted by the recalling firm
- Verify that all consignees have received notification about the recall and have taken appropriate action
- If not done, the firm is not meeting its obligation/responsibility to the consumer.
- 21 CFR 7.42(b)(3)

FDA ENFORCEMENT REPORT

- Contains a descriptive listing of each new recall, its classification, and the specific action being taken by the recalling firm.
- Does not include Market Withdrawals
- 21 CFR 7.50

FDA RESPONSIBILITIES

- Monitor the recall
- Assess a firm's recall strategy
- Classify the recall (Center)
- Terminate the recall

EFFECTIVE RECALL

- 100% of the product was retrieved by the firm or product accounted for
- “Effectiveness” checks were made
- Proper disposition action was taken
- Appropriate corrective actions taken to prevent similar occurrences

INEFFECTIVE RECALL ISSUES

- No recall notification
- The product is still held for sale
- No sub-recall notification
- No follow-up made to retrieve the product
- The product is NOT well quarantined

MONTHLY STATUS REPORT

- Date and method of notification, and number of consignees notified of the recall
- Number of consignees responding to the recall communication
- Number and results of effectiveness checks
- Number of products recovered and/or number of units corrected
- Disposition of returns and held stock
- Action taken to prevent similar occurrences
- Estimated date of completion of the recall

TERMINATION OF RECALL

- Final Status Report provided to FDA for review
- Written request for termination
- FDA's review revealed satisfactory completion and a written communication received

FDA MANDATORY RECALL AUTHORITY

- Section 423 of the FD&C Act which was added by section 206 of the FDA Food Safety Modernization Act of 2011 (FSMA): Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls | FDA

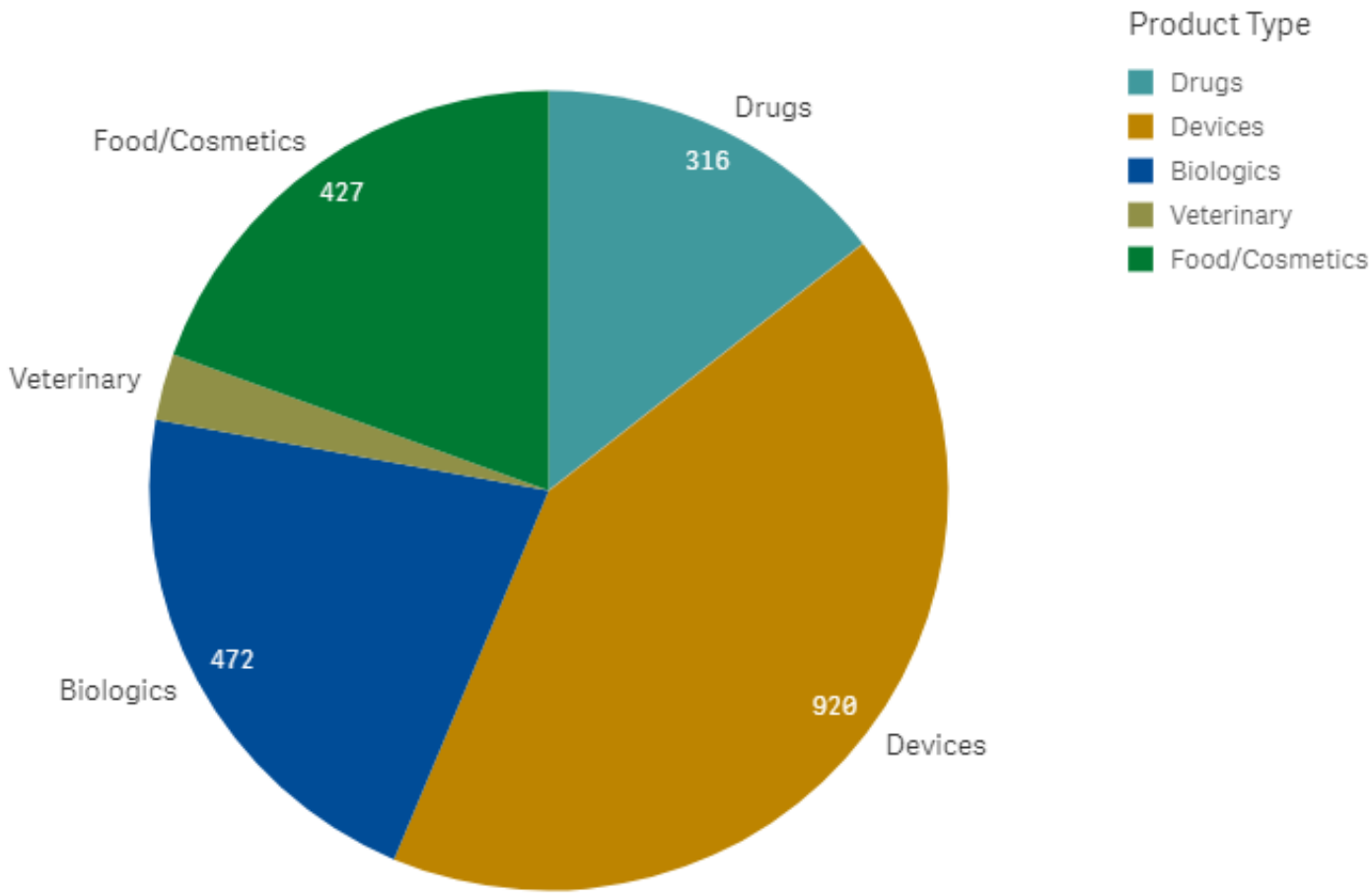
- Gives the FDA authority to order a responsible party to recall an article of food where the FDA determines that there is a reasonable probability that the article of food is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

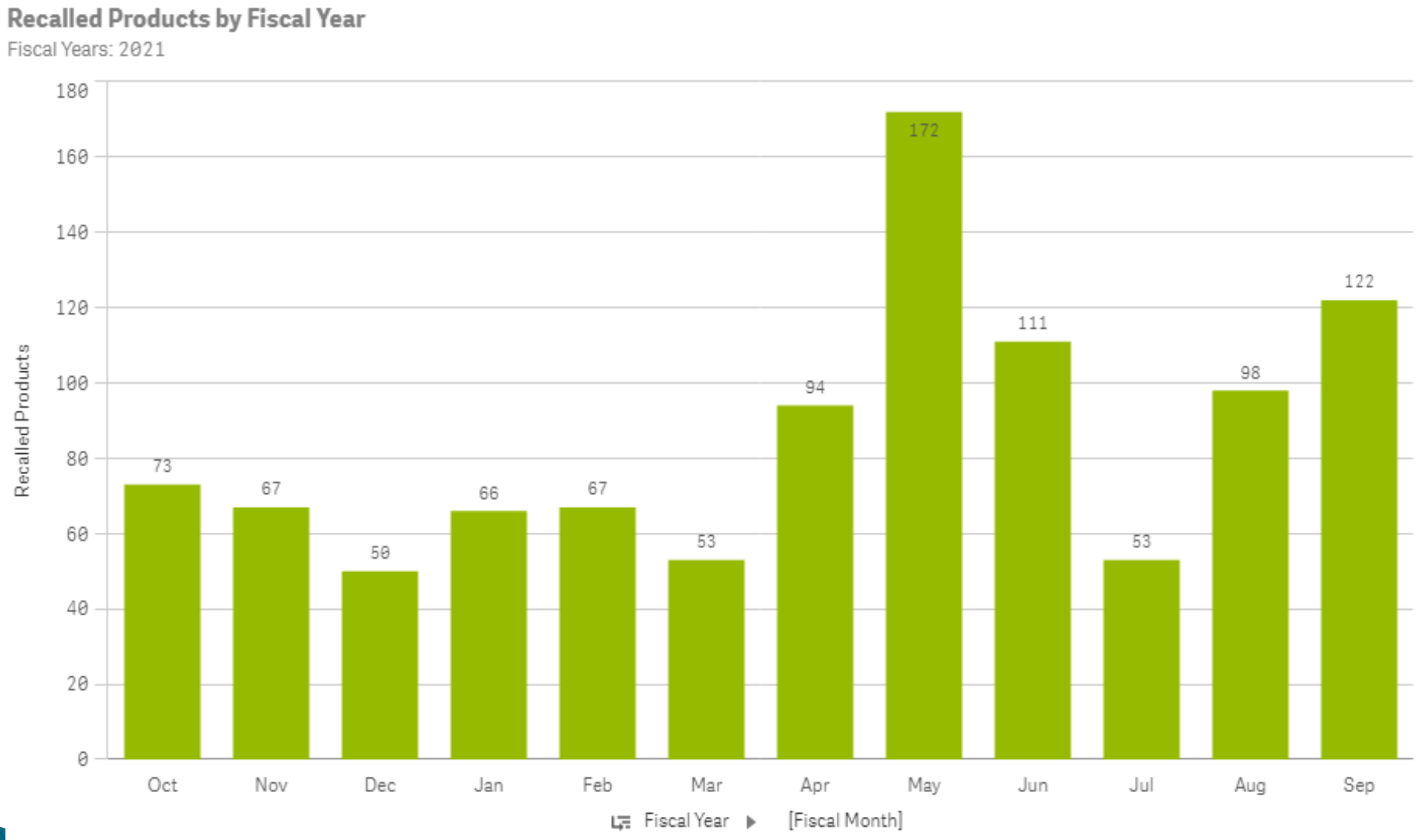
WHOLE GENOME SEQUENCING (WGS)

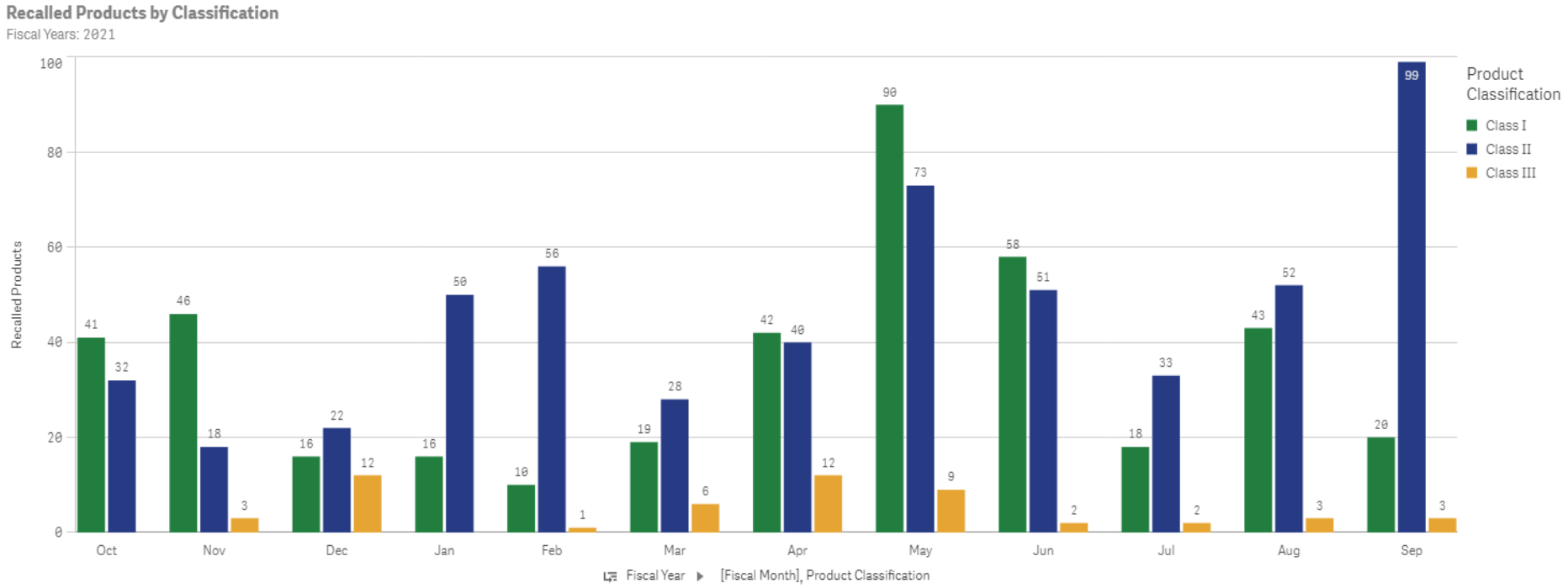
- A laboratory process that determines the complete DNA sequence of an organism's genome at a single time.
- Used to determine the pattern on the pathogen.
- Checked against the National Database to determine if it matches the pattern of known illnesses or outbreaks
- CDC will interview persons with known illnesses to help determine if a specific food was consumed that may be the cause of their illness.
- Whole Genome Sequencing (WGS) Program | FDA

Recall Events by Product Type

Fiscal Years: 2021




Recalled Products by Fiscal Year
Fiscal Years: 2021
Recalled Products
180
160
140
120
100
80
60
40
20
0
73
67
50
66
67
53
94
172
111
53
98
122
Oct
Nov
Dec
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Fiscal Year
[Fiscal Month]


Recalled Products by Classification
Fiscal Years: 2021
Recalled Products
100
80
60
40
20
0
41
32
46
18
3
16
22
12
16
50
10
56
1
19
28
6
42
40
12
90
73
9
58
51
2
18
33
2
43
52
3
20
99
3
Oct
Nov
Dec
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Fiscal Year
[Fiscal Month], Product Classification
Product Classification
Class I
Class II
Class III

Contact Information

Recall Coordinator
U.S. Food and Drug Administration
Division of Human & Animal Food West 5
E-mail: orahafwest5recalls@fda.hhs.gov