RECALL – The word that brings shudders to the food industry

Aurora A. Saulo, Ph.D. Professor and Extension Specialist in Food Technology University of Hawaii at Manoa aurora@hawaii.edu

May 4-6, 2010 Manila, Philippine

C/T/A/H/R College of Tropical Agriculture and Human Resources

Goal of the Food Industry

• To produce safe and wholesome foods





- Develop and follow programs
 - Identify products accurately
 - Document procedures
 - Validate results with third-party audits
- Know where your products come
 - from and where they go (traceability) Trace forward; trace back (product identification is key)
 - Raw materials, ingredients, packaging

 - During crisis, respond quickly

But sometimes, things go wrong... C/T/A/H/R College of Tropical Agriculture and Human Resources

And When Things Go Wrong

• Usually at very inconvenient times



Then It Hits the News (Noose)!

• Adverse publicity almost instantaneously



And Even If The Story Is Inaccurate, or Not Even True

You still get unwanted exposure:

"A lie can travel halfway around the world while the truth is putting on its shoes. " (Mark Twain)

C/T/A/H/R College of Tropical Agriculture and Human Resources

Public Health Issue-Botulinum Toxin





Public Health Issue-Salmonella

• Outbreaks: 2001, 2004

 Resulted in mandatory pasteurization of raw almonds by September 1, 2007



C/T/A/H/R College of Tropical Agriculture and Human Resources

2006 Spinach Outbreak

Spinach growers were warned about produce safety TAXA AND INC. THE R Over 200 illnesses and one death

C/T/A/H/R College of Tropical Agriculture and Human Resources



High Profile Outbreaks Jewell Dairy Salmonella (1985) Jalisco Cheese (1985) Jack-in-the Box E. coli 0157:H7 (1993) Schwann's Ice Cream Salmonella (1994) Japanese Radish Sprouts (1996) **Odwalla Apple Juice (1998)** Pre-Cut Spinach (2007) • Tomatoes then peppers (2008) C/T/A/H/R College of Tropical Agriculture and Human Resources







US FDA Recall Policy 21CFR7.40

- Recall: "...removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration."
- Therefore, recall is the

 Prompt removal of contaminated, mislabeled products, or sick animals from the market (includes proper disposal)

C/T/A/H/R College of Tropical Agriculture and Human Resources

US FDA Recall Policy 21CFR7.40 (cont'd)

• Objective of a recall: "...to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective."

C/T/A/H/R College of Hoppical Agriculture and Human Resources

US FDA Recall Policy 21CFR7.40 (cont'd)

- Voluntary action by food manufacturers and distributors
- "...an alternative to a FDA-initiated court action..."

Different from Seizures or Other Court-Actions

- That are done by US FDA when
 - Firm refuses to undertake a recall
 - A recall is ineffective
 - The agency believes a recall would be ineffective
 - Violation is continuing

C/T/A/H/R College of Tropical Agriculture and Human Resources

US FDA Enforcement Policy

- 21CFR7.41 21CFR7.59 (Guidance on policy, procedures, and industry responsibilities)
 - Sec 7.41 Health hazard evaluation and recall classification
 - Sec 7.42 Recall strategy
 - Sec 7.45 FDA requested recall
 - Sec 7.46 Firm initiated recall

C/T/A/H/R College of Tropical Agriculture and Human Resources

US FDA Enforcement Policy (cont'd)

- 21CFR7.41 21CFR7.59
 - Sec 7.49 Recall communications
 - Sec 7.50 Public notification
 - Sec 7.53 Status Reports
 - Sec 7.55 Termination
 - Sec 7.59 General industry guidance

C/T/A/H/R College of Tropical Agriculture and Human Resources

Health Hazard Evaluation and Recall Classification (21CFR7.41)

Ad Hoc FDA committee will determine

- Has disease or injury Who occurred? be ex
 Are there conditions – How
- that will expose humans or animals to a health hazard?
- Will humans or animals be exposed to a health hazard?
- Who are expected to be exposed?How serious are the
- hazards?
- What is the likelihood of occurrence?
- What are the consequences of occurrence?

C/T/A/H/R College of Tropical Agriculture and Human Resources University of Hawaii at Manoa

Health Hazard Evaluation and Recall Classification (21CFR7.41)

- Based on the assessment, a recall classification will be assigned relative to the degree of health hazard:
 - Class I
 - Class II
 - Class III

C/T/A/H/R College of Tropical Agriculture and Human Resources University of Hawa'i at Mānoa



C/T/A/H/R College of Tropical Agriculture and Human Resources Hawai! at Manna

Class I Recalls

• Reasonable probability that the use of, or exposure to, a violative product cause. serious adverse health consequences or death

- Examples: food pathogens, allergens
- Public warnings



}

C/T/A/H/R College of Tropical Agriculture and Human Resource

Class II Recalls

- Involve products that may cause temporary or reversible health consequences
- Probability of serious adverse health consequences is remote
- Public warning likely
- Intermediate effectiveness checks

C/T/A/H/R College of Tropical Agriculture and Human Resources

Class III Recalls

- May not involve public warning
- Wholesale or retail level
- · Effectiveness checks are minimal
- · Affected products have no health hazards



C/T/A/H/R College of Tropical Agriculture and Human Resources

Market Withdrawals

• This is a situation where no violation is involved or the violation is minor and product is not subject to seizure under current FDA or USDA policy or guidelines.

C/T/A/H/R College of Tropical Agriculture and Human Resources

Stock Recovery

- Involves the recovery of products that remain under the complete control of the manufacturer and its clients, regardless of the severity of the problems.
- For example, most of Multiple Organics products are dried, shelf stable ingredients. Such a retrieval could be possible.

C/T/A/H/R College of Tropical Agriculture and Human Resources

PUBLIC WARNING CLASSIFICATION RETRIEVAI LEVEL FFECTIVENE CHECKS Class I Consumer 100% at retail Yes 90 – 100% at Class II Retail or more Yes retail Class III Wholesale or Variable Sometimes more Withdrawal No Company Company Criteria Assessmen C/T/A/H/R College of Tropical Agriculture and Human Resources

Recall Summary





If Product is a Suspected Health Concern



The following actions must be started simultaneously:

- Confirm the presence or absence of a health concern
- Notify management
- Trace all suspect products
- Collect & review production or quality records
- "HOLD" product in company control

C/T/A/H/R College of Hawaii at Manoa

If Product is a Confirmed Health Hazard

DANGER

- Initiate recall
- Sales & Marketing Notify buyers; pick up product; isolate product
- Confirm coverage with insurance company
- Marketing Public relations
- Purchasing Work with suppliers if issue is supplier-related
- Human Relations Work with staff
- Production Assist in investigation; stop operations

C/T/A/H/R College of Tropical Agriculture and Human Resources University of Hawaii at Manoa

Firm-initiated Recall (21CFR 7.46)

- Firm should notify FDA with required information.
- Firm action will be considered by FDA as a recall when product involves a violation subject to legal action.

C/T/A/H/R College of Tropical Agriculture and Human Resources

FDA-requested Recall (21CFR7.45)

• Except in limited circumstances (e.g., infant formula), a firm need not initiate a recall even when at FDA's request.

Recall Strategy (21CFR7.42)

- = Recall Plan (entails a Recall Program)
- Should include
 - Depth of recall: level in the distribution chain (consumer, retail, wholesale)
 - Public warning: general or using specialized media
 - Effectiveness checks: level A (100%), level B (10-99%), level C (10%), level D (2%), level E (0)
 - C/T/A/H/R College of Tropical Agriculture and Human Resources

Recall Program

- Documented procedures developed and maintained by a Recall Coordinator
- Staff training
- Must be practiced regularly as
- a company
 - Goal: to have recalled products within 24 hours of first alert

C/T/A/H/R College of Tropical Agriculture and Human Resources

Recall Program => Addresses Recall Needs

- Assesses personnel needs
- Needs management support
- Needs a Recall Action Group Recall Action Coordinator
- Requires team effort

C/T/A/H/R College of Tropical Agriculture and Human Resources

Recall Action Team or Retrieval Team

- Coordinator
- Technical Representative - QA, R & D, Laboratory, Contractor
- Warehouse & Distribution

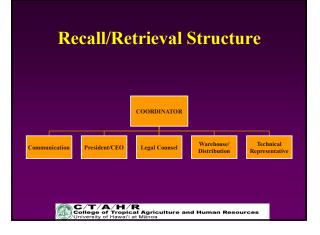
 Warehouse, receiving, distribution, marketing, customer service
- Communication
- Legal

C/T/A/H/R College of Tropical Agriculture and Human Resources

Recall Action Team or Retrieval Team (cont<u>'d)</u>

- President/CEO
- Financial Staff
- Public Relations
- Legal Staff
- Outside Help (if needed)





How to Recall the Product

- When out-of-compliance food inadvertently reaches any part of the food chain, including the consumer, the product needs to be recalled.
- Traceback or tracking systems or traceability
 - Used to trace the route of contaminated food or sick animals in the food chain

C/T/A/H/R College of Tropical Agriculture and Human Resources



Traceback or Tracking Systems or Traceability

- Initiated by the food producer or manufacturer
- Offer additional safety reassurances to food
- Used in post-market monitoring (e.g., unintended health effects)
- Important in insuring liability and compensation

C/T/A/H/R College of Tropical Agriculture and Human Resources

Recall & Traceability

- Statutorily required of some products but all products must involve these.
- Protect the business
- Different issues for distributor than a producer
 - Reliance on vendors & warehouse operations
 - Lot sizes may be variable
 - Mixed pallets

C/T/A/H/R College of Tropical Agriculture and Human Resources

Commitment to Traceability

 Needs total management support



C/T/A/H/R College of Tropical Agriculture and Human Resources

How to Trace the Product

• **Product identification** is critical in tracing the product through distribution from supplier to consumer.

• Rigid coding system preferred

Test the system through mock

recalls

- system through mock
- Evaluate performance at post mock-recall meetings

C/T/A/H/R College of Tropical Agriculture and Human Resources

Product ID → Tracking → Recall

- Proper identification of product is a prerequisite to tracking & recall.
- Plan ahead. A crisis is not the time to find that your recall program doesn't work.

APPENDIX 13

Required Label Information

C/T/A/H/R College of Tropical Agriculture and Human Resources

- Legibility
- Establishment
- Product
- Pack Date
- Pack Year
- Shift or Period





Identifying **Initial Source**

 Critical information Use accurate and recorded product identifications linking successive packaging and transport/storage configurations.





C/T/A/H/R College of Tropical Agriculture and Human Resources

Other Product Information • Product type Packaging • Labeling • Shelf life Lot number Date processed/received/rotated Inventory Shipping and handling information C/T/A/H/R College of Tropical Agriculture and Human Resources



Case Codes & Pallet Tags

- Case codes should be the same as for individual product containers
- Universal Product Codes (UPC) & scanners may be used for tracking
- Pallet tags should delineate what is in pallet



EDWANSO Sk

C/T/A/H/R College of Tropical Agriculture and Human Resources

Tracking Finished Product

OBJECTIVE: To ensure that all products shipped by the firm may be tracked to the customer in the event that there are problems. This procedure shall be used for tracking products as part of a recall exercise.

DEVELOP & USE YOUR TRACKING FORM

RECALL AND TRACKING FORM	
CORFACT MARKE IN 1995 (20 Mar Higher And Andreas Andreas Handreas Andreas Andreas Handreas Andreas Handreas Andreas Handreas Andreas	
/T/A/H/R lege of Tropical Agriculture and Human Resources rersity of Hawa'ii at Mānoa	







Mock Recall (cont'd)

- Be proactive
- Seamless, not a fire fighting exercise
- Have backups



C/T/A/H/R College of Tropical Agriculture and Human Resources

Recall Communications (21CFR7.49)

- Lists the necessary information for a recall
- Gives instructions on product handling

C/T/A/H/R College of Tropical Agriculture and Human Resources

Role - Communications

- Responsible for communicating with the media, consumers, and regulatory Agencies
- Instructs all employees to refer all questions to Communications
- Statements are pre-evaluated and preapproved by the Recall Action Team and Legal Counsel

C/T/A/H/R College of Tropical Agriculture and Human Resources

Contact List

- Detailed contact lists shall be developed, documented and maintained on a regular basis.
- Quarterly at least
- All team members
- All warehouse and distribution centers
- All clients
- All vendors

C/T/A/H/R College of Tropical Agriculture and Human Resources

Communicating the Problem Radio, television, & print media Full details on product State what is known and NOT known and what the company is doing to address uncertainties Instructions on how to handle suspect product Be open & honest

Group Exercise

- Recall Action Team Members:
 - Take 15 minutes to jot down your duties
 - Include types of documents, locations and key contacts
 - This will become the basis of your work instruction.
 - Discuss the duties

Public Notification (21CFR7.50)

- Published in the weekly FDA Enforcement Report <u>http://www.fda.gov/Safety/Recalls/Enforc</u> <u>ementReports/default.htm</u>
- Then click on Recalls, Market Withdrawals, & Safety Alerts



C/T/A/H/R College of Tropical Agriculture and Human Resources

Recall Status Reports (21CFR7.53)

- By the initiating firm to the FDA usually at 2-4 week intervals
- Discontinued upon termination of the recall



Recall Termination (21CFR7.55)

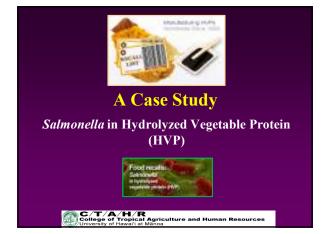
- Depends on the hazard
- By FDA when all reasonable efforts had been made to remove or correct the product
- Requested by the firm demonstrating effectiveness of the recall

C/T/A/H/R College of Tropical Agriculture and Human Resources

General Industry Guidance (21CFR7.59)

- Prepare a contingency plan and test its effectiveness
- Use product identification that will positively identify the lot and facilitate effective removal of violative lots
- Keep records beyond product shelf life and expected use (e.g., 3 years total)

C/T/A/H/R College of Tropical Agriculture and Human Resources



Salmonella in HVP

- Considered a major product recall due to public health impact (*Salmonella* Tennessee)
 Used worldwide in many products
- Given expanded coverage on
 <u>http://www.fda.gov/Safety/Recalls/MajorPr
 oductRecalls/HVP/default.htm</u>
- February-April 2010
- Some say it is potentially the largest recall in US history

C/T/A/H/R College of Tropical Agriculture and Human Resources University of Hawla'l at Manoa

Salmonella Tennessee Symptoms - Fever - Diarrhea (may be bloody) – Nausea - Vomiting - Abdominal pain - If the organism enters the bloodstream, may cause arterial infections Can survive in dry products C/T/A/H/R College of Tropical Agriculture and Human Resources



Some HVP Applications Beef Dips Chicken Salad dressings Pork Spice rubs Snacks Seasonings Soups Stews Gravv Sauces C/T/A/H/R College of Tropical Agriculture and Human Resources

The HVP Recall

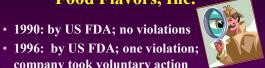
- HVP by Basic Food Flavors, Inc.
 - in liquid and paste forms manufactured after September 17, 2009
 - Including foods using this HVP if not cooked before serving (e.g., snacks, dips)
- As of March 24, 2010, no foodborne illness from this HVP or products using this HVP had been reported.

C/T/A/H/R College of Tropical Agriculture and Human Resources

Inspection History of Basic Food Flavors, Inc.

• 1990: by US FDA; no violations

company took voluntary action



• 2009: by a State contractor; no violations

C/T/A/H/R College of Tropical Agriculture and Human Resources

Law on Reporting Problems with Food

- September 2009: US FDA established the **Reportable Food Registry (RFR) that** mandates food industry to report within 24 hr of detection any problems with a food product
- February 5, 2010: Upon testing HVP purchased from Basic Food Flavors, Inc., a customer reported detection of Salmonella.

Inspecting Agency's Response

• February 12, 2010: US FDA and the Nevada State Health Department began investigations



- Also found Salmonella in the processing plant
- Set up a database of products containing this HVP

with Salmonella Tennessee

http://www.accessdata.fda.gov/scripts/HVPCP/

C/T/A/H/R College of Tropical Agriculture and Human Resources

Inspecting Agency's Response (cont'd)

- March 4, 2010: US FDA issued a press release about the firm-initiated recall
 - Industry must destroy or recondition recalled this bulk HVP
 - Recall foods containing this HVP
 - Issued consumer instructions
 - Check list of recalled products on FDA website
 - · Follow cooking instructions for all foods
 - Report symptoms of foodborne illness
 - C/T/A/H/R College of Tropical Agriculture and Human Resources

Inspecting Agency's Response (cont'd)

• April 1, 2010: about 177 products containing this HVP have been identified



- Database is searchable by brand name, product name, or a combination
- Each product (e.g., bouillon, frozen food, gravy mix, sauce and marinade, etc.) may have been manufactured by several DFOCCESSOFS. C/T/A/H/R College of Tropical Agriculture and Human Resources



- Brands included – McCormick
 - Great Value
 - Trader Joe's

– Herbox

- Publix

- Kroger

- Dean's

- Garden Harvest

- Great Nut Supply

- French's
- Pringles

– Durkee

- Ouaker
- Safeway
- Fresh Food Concepts
- Hawaiian

C/T/A/H/R College of Tropical Agriculture and Human Resources



Inspection Form 483 (cont'd)

- January 21, 2010: company received COA showing positive for Salmonella
- January 21-February 15: company continued distribution
- January 21-February 20: company continued manufacture under the same conditions without microbial
- contamination control Source:http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/ucm2 03784.htm College of Tropical Agriculture and Human Resources

Inspection Form 483 (cont'd)

- Detailed significant issues in the plant
 - Lack of microbial contamination control during
 - manufacture, packaging, and storage of foods - Failure to conduct cleaning and sanitation procedures
 - Inadequately installed plumbing and inadequate drainage
 - Plant construction and design do not allow floors to be adequately cleaned and kept in good repair.

Source:http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/ucm2 03784.htm

C/T/A/H/R College of Tropical Agriculture and Human Resources

Basic Food Flavors' HACCP Plan

CCP HACCP Plan Summary		Review Date March 2009 SUPERCEDES				PRODUCT HVP – VACCUM DRIED POWDER PAGE 1 of 1			
Critical Limits		Monitoring				Corrective Action	CCP Verification Procedures	Records	
		What	How	Frequency	Who	1			
		a 8 hours a pH 5.8	pH & Time during treatment . Check the pH	Sample is taken and pH checked using pH meter	Before treatment and then after every 4 hours	Reaction Operator	If pH is < 8.7 raise pH by adding more Caustic (NaCH). If Treatment they friess than 8 hours treat it to 28 hours.	-Calibrating the pH used in determining the pH. - Observing monitoring solutivities to ensure the records are completed and to verify that the documented values are estimat the sections, -Observing corrective and appropriate action taking, - Reviewing records including verifying signatures and dates for completeness.	-Treatmer Log pH Calibration Log.



Flavors-denics-wrongdoing-in-HVP-recall

Basic Food Flavors' Response (cont'd) Company's sales and marketing manager

- hoped media freeze "would help publicity of the recall to pass quickly."
 - "Quite honestly, we didn't bother answering the press because we just wanted it to go away," he said. "...It's working. It's beginning to die down. The recall affected "only 10,000 lb of 10 million" or
 - 0.1% of the production volume of the company.

Source: http://www.foodproductiondaily.com/Quality-Safety/Basic-Food-Flavors-denies-wrongdoing-in-HVP-recall Agriculture and Human Resources

Basic Food Flavors' Respon (cont'd)



 March 17, 2010: Company broke its media freeze to FoodNavigatorUSA "While it is unclear whether FDA is suggesting in the Form

483 that Basic Foods knowingly shipped adulterated product, the language used by the agency and reported by the press has created that implication. We, therefore, consider it important to clarify that Basic Foods has not knowingly shipped into commerce any product the Company believed had the potential to contain Salmonella."

ource: http://www.foodnavigator-usa.com/Financial-Industry/Basic-Food Flavors-denies-wrongdoing-in-HVP-recall College of Tropical Agriculture and Human Resources

Basic Food Flavors' Response (cont'd)

• Form 483 of the company issued March 9, 2010 by the US FDA (FoodNavigatorUSA)

"After receiving the first private laboratory analytical results [dated January 21] indicating the presence of Salmonella in your facility, you continued to distribute HVP paste and powder products until 2/15/2010. Furthermore, from 1/21/2010 to 2/20/2010, you continued to manufacture HVP paste and powder products under the same processing conditions that did not minimize microbial contamination.

ource: http://www.foodnavigator-usa.com/Financial-Industry/Basic-Food-Flavors-denies-wrongdoing-in-HVP-recall

Basic Food Flavors' Response (cont'd)

- Their website does not contain any progress report on the recall. There is no information on:
 - Company responses to the recall
 - What the company is doing to insure no product contamination in the future



- What stage the recall is at

C/T/A/H/R College of Tropical Agriculture and Human Resources

Unwanted Exposure (cont'd)

• The Daily Green, April 27, 2010. "HVP, a Non-Food, Continues to Cause More Food Recalls"

hedailygreen the consumer's prote

- "...the industrialized food system and how easily it can sicken us, rather than nourish us.'
- "...food manufacturers, it doesn't sound like a farm, does it?
- ...how weirdly disgusting our food system is." C/T/A/H/R College of Tropical Agriculture and Human Resources



Unwanted Exposure (cont'd)

• March 13, 2010 Pacifica Riptide

"They documented dirty utensils and equipment-mixers and tubing coated with brown residue-and cracks and fractures in the floor, as well as standing water on the floor-all conditions where bacteria can breed. In one area where paste mixers and belt dryers were positioned, FDA inspectors noted "<u>standing, grey/black liquid</u>" in the drain near the area where the hydrolyzed vegetable protein was turned from paste to powder. "We sensed an <u>odor</u> in the vicinity of this drain," the inspectors wrote. Enough said? "

Source: http://www.pacificariptide.com/pacifica riptide/ C/T/A/H/R College of Tropical Agriculture and Human Resources

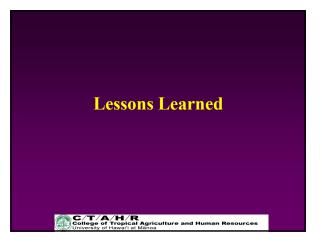
Unwanted Exposure (cont'd)

• March 12, 2010 Care2 Healthy and Green Living

"We will now attempt to scare you into walking away from the processed food. "

"Thousands of types of processed foods-including many varieties of soups, chips, frozen dinners, hot dogs and salad dressings-may pose a health threat because they contain a flavor enhancer that could be contaminated with salmonella.

Source: http://www.care2.com/greenliving/hvp-biggest-food-recall-in-ushistory.html



How the US FDA Minimized the **Risk of Foodborne Illness**

- Immediately began investigations after report of detection of Salmonella on RFR
- Communicated with the company
- Issued press release about the recall

FD U.S. Food and Drug Administration

How the US FDA Minimized the Risk of Foodborne Illness (cont'd)

- Set up online Q&A for consumers, Q&A for the industry
- Set up online database of recalled products and brands
- Posted online public documents about the investigation and recall
- Posted online appropriate contacts

C/T/A/H/R College of Tropical Agriculture and Human Resources

How the Company Minimized the Risk of Foodborne Illness

- Voluntarily recalled all involved products but not sufficiently timely
 - Form 483 cited their continuing to manufacture and distribute for more than 3 weeks after receiving confirming lab results of *Salmonella*



To Minimize the Risk of Foodborne Illness, the Company Should Have...

- Known what to do when the investigators knock
- Ceased production and distribution while confirming lab results
- Had a tested Crisis Management Program and a trained Crisis Management Team

C/T/A/H/R College of Tropical Agriculture and Human Resources

To Minimize the Risk of Foodborne Illness, the Company Should Have...

- Had tested Recall Program and a trained Recall Team
- Announced recall to the industry and the consumers immediately upon verification (in different languages)
- Publicized on their website events and activities related to the recall

C/T/A/H/R Diverse of Tropical Agriculture and Human Resources University of Hawai1 at Manoa

To Minimize the Risk of Foodborne Illness, the Company Should Have...

• Promptly returned media calls (only by designated company communication persons)



- Within the company
 - Checked coverage of insurance policy
 - Reviewed supplier qualification procedures
 - and supply contracts
 - Obtained criminal law advice
 - C/T/A/H/R College of Tropical Agriculture and Human Resources University of Hawalti at Manoa

Communicating the Problem Radio, television, & print media Full details on product State what is known and NOT known and what the company is doing to address uncertainties Instructions on how to handle suspect product Be open & honest

C/T/A/H/R College of Tropical Agriculture and Human Resources University of Hawaii at Manoa

Group Exercise

- Recall Action Team Members:
 - Shall we do a mock recall?
 - Use your notes from the first exercise and let's go.
 - Select a product to track.

C/T/A/H/R College of Tropical Agriculture and Human Resources Thanks to Jennifer Thomas of US FDA for her kind assistance.

