



# ***Crisis Management Teams A Key Resource for Any Recall***

***Matt Mathison  
June 9, 2011***



# Topics Covered Today

- Initial Overview of Recall Process
- Current Food Safety Regulatory Environment
- Crisis Management Teams
- Dairy Industry Resources



# FDA Recall Classifications

## ■ Product Recall

- ◆ A product in violation of FD&C Act (Adulterated or Misbranded)
- ◆ Product already in distribution channels
- ◆ Is subject to legal action by FDA

## ■ Market Withdrawal

- ◆ A product not in violation of FD&C Act (Adulterated or Misbranded)
- ◆ Product already in distribution channels
- ◆ Is not subject to legal action by FDA

## ■ Stock Recovery

- ◆ Involves product that has not been marketed or not left the direct control of the firm (including outside warehouses)

**Source: Belinda Clifton, Regional Milk Specialist Pacific Region, FDA  
DMI Webinar Presentation – February 25, 2011**

# FDA Recall Classifications

- Class I Recall
  - ◆ Reasonable probability of serious adverse health consequences/death
- Class II Recall
  - ◆ May cause temporary or medically reversible adverse health consequences
- Class III Recall
  - ◆ Not likely to cause adverse health consequences

Source: Belinda Clifton, Regional Milk Specialist Pacific Region, FDA  
DMI Webinar Presentation – February 25, 2011

# Recall Types [Initiation]

- Company – Initiated (voluntary)
- FDA Requested Recall
- FDA Mandated Recall

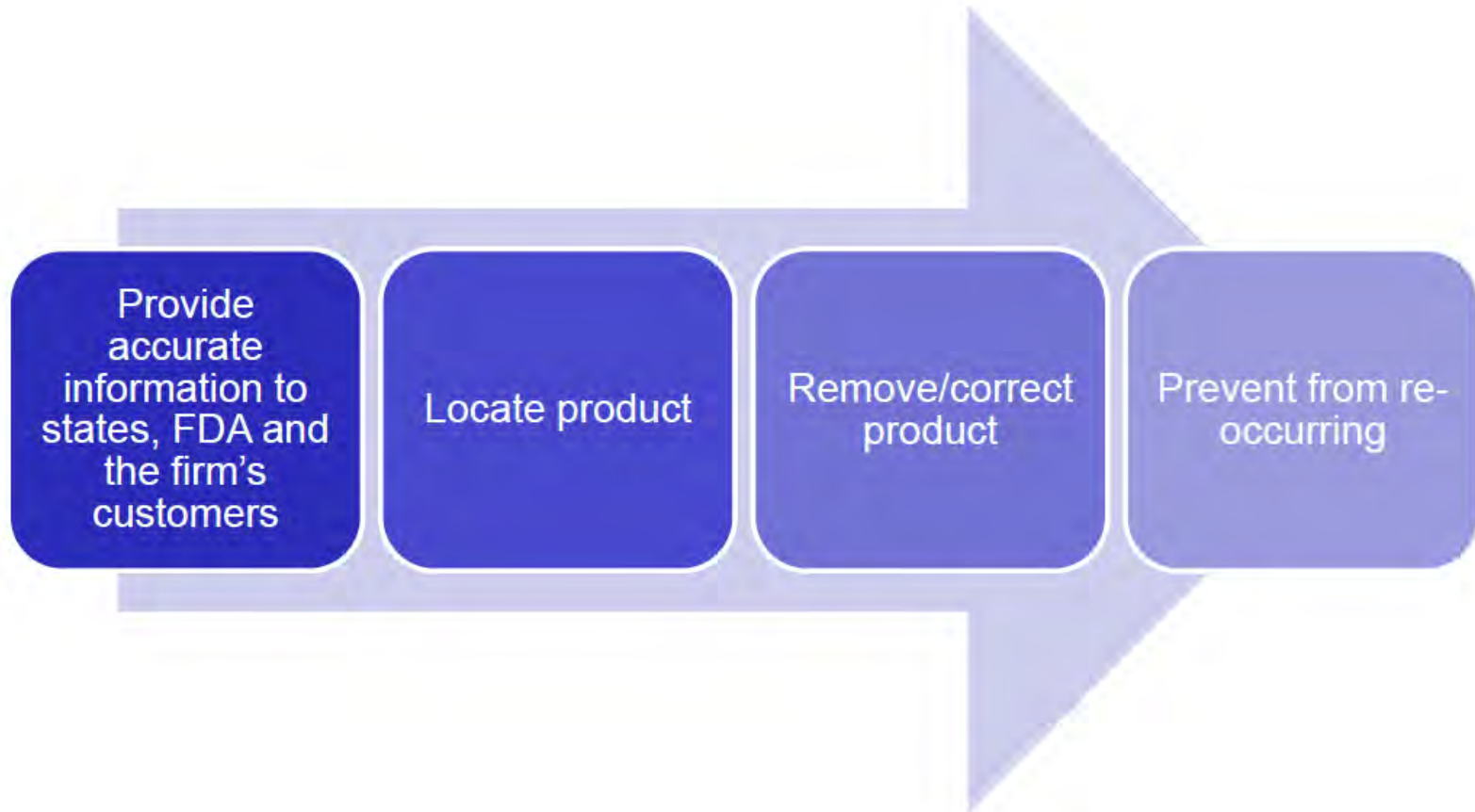


The screenshot shows the FDA website page for 'Industry Guidance Information on Recalls of FDA Regulated Products'. The page is part of the 'Safety' section under 'Recalls, Market Withdrawals, & Safety Alerts'. The main heading is 'Industry Guidance Information on Recalls of FDA Regulated Products' with a last update date of 2-6-2009. The page lists several resources:

- Industry Recall Guidance: Product Recalls, Including Removals and Corrections
- Recalls Background and Definitions
- Index of Model Press Releases:
  - Allergens (Allergy Alert)
  - Listeria monocytogenes
  - Clostridium botulinum
  - Salmonella (all serotypes)
    - Pet Food and Pet Treats
  - E. coli O157:H7
  - Medical Device
- District Recall Coordinators
- Index of Model Letter Exhibits in FDA Regulatory Procedures Manual:
  - 7-1 - Effectiveness Check Letter

Source: Belinda Clifton, Regional Milk Specialist Pacific Region, FDA  
DMI Webinar Presentation – February 25, 2011

# Company's Recall Objectives



Source: Belinda Clifton, Regional Milk Specialist Pacific Region, FDA  
DMI Webinar Presentation – February 25, 2011

# Company's Recall Actions

Notify state and FDA district office Recall Coordinator

Determine potential threats to consumer safety

Develop a recall strategy and communication with the Recall Coordinator BEFORE implementing it

Investigate cause and remedy problem (reason for recall)

Share distribution list/product description

Source: Belinda Clifton, Regional Milk Specialist Pacific Region, FDA DMI Webinar Presentation – February 25, 2011

# Company's Recall Actions

## FDA Objectives

- Consumer protection
- Compliance
- Assist firms in conducting effective recall to completion
- Monitor firm's recall
- Assess adequacy of a firm's action

## What to Report

- Product/code(s)/lot number(s)
  - Recalling firm manufacturer (if different from recalling firm)
- Reason for recall/source of problem
- Volume of product produced
- Volume of product in commerce
- Distribution pattern
- Firm's recall strategy

## Recall Documents

- Product label
- Recall notification letter
- Distribution list
- Product catalog (if any)
- Consumer complaint(s)
- Test result(s)/analytical data
- Health risk assessment (if any)
- Product QA, SOP changes, etc.
- Press release (if any)

**Source: Belinda Clifton, Regional Milk Specialist Pacific Region, FDA DMI Webinar Presentation – February 25, 2011**



# Regulatory Environment

## ■ Bioterrorism Act of 2002

## ■ FSMA

## ■ Reportable Food Registry

U.S. Department of Health & Human Services | www.hhs.gov

FDA U.S. Food and Drug Administration

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Food

Food Defense & Emergency Response

Regulatory Information

Administrative Detention

### Administrative Detention

#### FDA Actions on Bioterrorism Act of 2002 Legislation

- **Press Release:** FDA Finalizes Rule on Administrative Detention of Suspect Food; Final Rule Increases Security and Safety of U.S. Food Supply May 27, 2004
- **Final Rule:** Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 June 4, 2004
- **Fact Sheet:** FDA's New Food Bioterrorism Regulation Final Rule: Administrative Detention May 27, 2004
- **Booklet (SECG):** What You Need to Know About Administrative Detention of Foods November 2004 Booklet: What You Need to Know About Administrative Detention of Foods November 2004
- **Slide Presentation:** Overview of Records and Administrative Detention Proposed Regulations Implementing the Bioterrorism Act 2004 (Available in Spanish)
- **"Dear Colleague" Letter** on Administrative Detention Final Rule May 27, 2004

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Food

Food Safety

Food Safety Programs

Reportable Food Registry

Technical FAQs

### Reportable Food Registry for Industry

For Industry: Submit a Report

For Consumers: Contact FDA

#### Spotlight

- Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007
- Reportable Food Registry (RFR) At a Glance (PDF - 89KB)

#### Resources for You

- Food and Drug Administration Amendments Act (FDAAA) of 2007
- Sec. 417, [21 USC 350f] Reportable food registry.

#### About the Reportable Food Registry

The Reportable Food Registry (RFR or the Registry) is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. The Registry helps the FDA better protect public health by tracking patterns and targeting inspections. The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-085), section 1005 directs the FDA to establish a Reportable Food Registry for Industry. The RFR applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula.

#### Who Should Use the Reportable Food Registry?

- About the Reportable Food Registry
- Who Should Use the Reportable Food Registry?
- Where Should Consumers, Food Retailers and Food Service Operators Report a Problem with Food?
- More Information

#### Contact Us

RFR Center for questions about policies, procedures and interpretations  
RFRSupport@fda.hhs.gov

RFR Help Desk for technical and computer-related questions about the RFR electronic portal  
RFRTechSupport@fda.hhs.gov

U.S. Department of Health & Human Services | www.hhs.gov

FDA U.S. Food and Drug Administration

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Food

Food Safety

Food Safety Modernization Act (FSMA)

### FDA Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4th, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it. Check back regularly for updates and new information related to the Act and what FDA is doing in response. Information will be posted as it becomes available.

Get FSMA Updates by E-mail

#### Improving Recall Information for Consumers

FSMA calls for a more consumer-friendly recall search engine and FDA has responded. The new law also gave FDA authority to order a food recall in certain circumstances. Recalls, mandatory or otherwise, are serious and we encourage consumers to pay close attention when recalls are announced. **More >**

#### Resources for You

- Recalls, Market Withdrawals, & Safety Alerts

#### CURRENT OUTREACH

**NEW FSMA Public Meeting Monday | June 6, 2011**

**Focus on Inspections and Compliance**

**Register Now - Space is Limited**

3 of 3

# Crisis Management Advanced Planning

- Establish a Crisis Management Team for company
- Develop and maintain a written plan:
  - ◆ Formalizes responsibilities and accountability
  - ◆ Minimizes redundancies and/or turf battles
  - ◆ Facilitates decision-making – ability to take immediate action if a crisis occurs [then continued action]
  - ◆ Enables continuity of tactical response
  - ◆ Helps streamline internal communications

Source: DMI/IDFA Crisis Preparedness Toolkit - 2009

# Crisis Management Advanced Planning

- Written Crisis Management Plan should include:
  - ◆ Ability to respond immediately [24/7]
  - ◆ Guidelines for receiving crisis information
  - ◆ Effective internal communication systems
  - ◆ Procedures to deal with regulatory officials
  - ◆ Listing of resources
  - ◆ Check insurance coverage

Source: IDFA Inspection Manual with FDA Recall Guide and Company  
Crisis Management Plan - 2011

# Crisis Management Team

## ■ CEO/COO/CFO

- ◆ Acts as Crisis Response Team leader/appoints someone to lead team
- ◆ May serve as company spokesperson

## ■ Media Coordinator/Spokesperson

- ◆ Coordinates company response to media inquiries and updates team regularly
- ◆ Either acts as or coordinates with lead company spokesperson
- ◆ Identifies appropriate third-party experts

## ■ Head of Sales/Marketing or Member Relations

- ◆ Coordinates outreach to customers, shareholders and/or members
- ◆ Answers questions or concerns
- ◆ Monitors market for impact on sales and/or crisis progression

# Crisis Management Team

## ■ Head of Manufacturing/Operations

- ◆ Leads company's operations response in coordination with Communications/PR
- ◆ Ensures that business operations are efficient and effective during the crisis
- ◆ Analyzes and reworks existing business processes affected by the crisis

## ■ Scientific/Technical Experts/Head of Quality Assurance

- ◆ Provides technical perspective and information on production procedures, composition of product
- ◆ Analyzes and translates test results and tracking information
- ◆ Liaises with Quality Assurance team to make recommendations on assuring product safety given the current scenario
- ◆ May serve as technical spokesperson

# Crisis Management Team

## ■ Head of Human Resources/Internal Communications

- ◆ Informs employees of procedures and expectations
- ◆ Disseminates up-to-date and accurate information to employees
- ◆ Fields questions and concerns from employees
- ◆ Assesses staffing needs to support long-term crisis response

## ■ Head of Public Affairs/Government Relations

- ◆ Coordinates with key government agencies and officials
- ◆ Assures company is current on FDA guidelines and government actions
- ◆ Manages non-technical requests and inquiries from state and federal government representatives
- ◆ Manages government requests for technical information or action in coordination with Quality Assurance team

Source: DMI/IDFA Crisis Preparedness Toolkit - 2009

# Crisis Management Team

## ■ **General Counsel and/or outside legal counsel**

- ◆ Advises on the legal implications of company actions and public statements

## ■ **Head of PR/Communications and/or outside PR counsel**

- ◆ Leads communications response in coordination with head of Manufacturing/Operations
- ◆ Identifies and prioritizes actions based on information from the Crisis Response Team
- ◆ Leads development of key messages and statements, prioritizes key audiences and ensures message delivery
- ◆ Liaises with Dairy Management Inc. (DMI)/dairy organizations to share updates and coordinate messaging and media responses

# Recall Management Advanced Planning

- Prepare a Written Recall Management Plan:
  - ◆ Establish Recall Management Team
  - ◆ Designate Recall Coordinator
  - ◆ Train corporate spokesperson
  - ◆ Review and rehearse the Plan
- Implement comprehensive Quality Assurance and HACCP Systems
- Audit the HACCP and QA Systems regularly

Source: IDFA Inspection Manual with FDA Recall Guide and Company Crisis Management Plan - 2011

# Recall Management Response

- Recall Submission to FDA through your local District Recall Coordinator (Minneapolis District: Kristine Zuroski)
  - ◆ Product information
  - ◆ Product codes
  - ◆ Recalling firm:
    - Firm name and “type”
    - **Contacts for recalling firm**
  - ◆ Manufacturer (if different) of product(s)
  - ◆ Identify firm responsible (if different)

Source: Guidance for Industry: Product Recalls, Including Removals and Corrections  
<http://www.fda.gov/Safety/Recalls/industryguidance/ucm129259.htm>

# Recall Management Response

- Recall Submission to FDA (cont.)
  - ◆ Reason for the recall
  - ◆ Health hazard assessment
  - ◆ Volume of recalled product(s)
  - ◆ Distribution pattern
    - **Provide consignee list to FDA**
  - ◆ Recall strategy

Source: Guidance for Industry: Product Recalls, Including Removals and Corrections  
<http://www.fda.gov/Safety/Recalls/industryguidance/ucm129259.htm>



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# Recall Management Response

## ■ Public Notification

- ◆ **Press release(s)**
  - Consult with FDA - DRC
- ◆ Written recall notification letters
  - Product ID
  - Description of problem
  - Depth of recall
  - Instructions to customers

Source: Guidance for Industry: Product Recalls, Including Removals and Corrections  
<http://www.fda.gov/Safety/Recalls/industryguidance/ucm129259.htm>



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# Recall Management Response

- Evaluation of the recall
  - ◆ Effectiveness of the recall
  - ◆ Recall status reports
  - ◆ Root cause analysis
  - ◆ Corrective actions
  - ◆ Termination of the recall

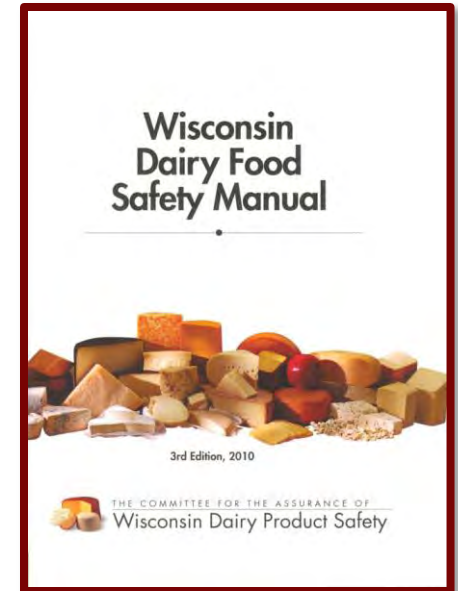
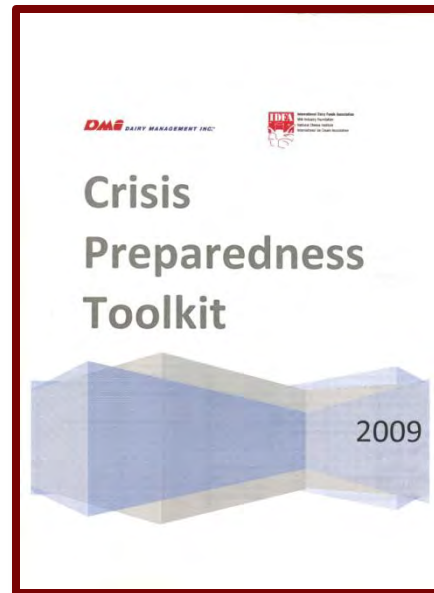
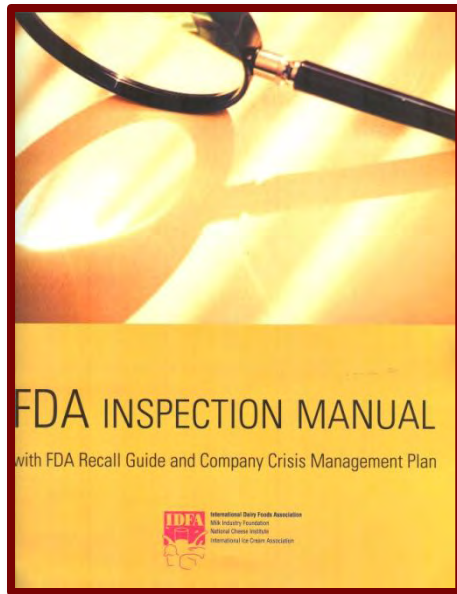
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# Resources for WI Dairy Companies

- Wisconsin Dairy Food Safety Manual
- DMI Crisis Preparedness Toolkit
- IDFA Inspection Manual



# Wisconsin Agro-Security Resource Network

## Protecting Our State's Food and Agriculture

Home

WARN Board and Members

Issues

Event Calendar

Resources

Press

Contact Us

The Wisconsin Agro-Security Resource Network (WARN) is a network of agriculture and government groups whose goals are to:

- Facilitate an industry-wide awareness and response to an animal health emergency or crisis incident involving Wisconsin agriculture.
- Quickly disseminate scientific, accurate information to media, producers and industry groups and consumers.
- Maintain consumer confidence in Wisconsin's food products and U.S. food safety systems.



Food and agriculture is critical to the economic health of Wisconsin, representing \$59 billion dollars in economic value to the state. Safeguarding this critical industry requires a coordinated, organized effort between industry groups and government agencies. To achieve this coordinated approach, Wisconsin agriculture came together to form WARN as a way to safeguard our diverse industry.

WARN is an industry-driven organization that has a network of agricultural and food safety professionals who can communicate to consumers and industry stakeholders in concert with regulatory officials in the event of a crisis affecting Wisconsin food and agricultural systems. WARN facilitates emergency preparedness between the agricultural sectors and government agencies. WARN also serves as a coordination center and educational forum for private sector crisis preparedness materials and training for agro-security related programs.

Having a seamless, coordinated communications plan in place along with government agencies during an incident is of paramount importance. The only way to "communicate with one voice" is through advanced planning and having key messages already prepared. Understanding the roles and responsibilities of the responding agencies helps industry groups better communicate the facts to consumers, customers, the news media and other key audiences.





- Resources
- Communication Tools
- Feedback
- Login

Welcome to the Dairy Response Center, a site initiated by the dairy checkoff and designed to help dairy producers communicate with others about animal health issues. While the site focuses primarily on communications tools, it also offers links to relevant animal health information.

The links are designed to provide background information only; if you have specific animal health questions, contact your state veterinarian or go to [www.aphis.usda.gov](http://www.aphis.usda.gov). We've also included a feature to contact us with any feedback you have about this site.

## Resources

Quickly locate information about Foot-and-Mouth, BSE and Johne's Disease. Educate yourself about animal cloning and biosecurity issues.

## Communication Tools

Whether you're talking to reporters or families touring your farm, the tools found here can help.

## Feedback



## Dairy Industry EMERGENCY RESPONSE CENTER

- [Message Center](#)
- [Media Log](#)
- [Home](#)

Search  [Go](#)

[Sign In](#)

[Current Situation](#)

[Roles & Responsibilities](#)

[Checklists & Protocols](#)

[Media Relations](#)

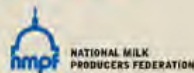
[Real-time Response](#)

[Response Toolkits](#)

[Other Resources](#)

[Contacts](#)

Website brought to you by:



Welcome back **Matt** | If you are not Matt, [click here](#).

### Response Toolkits Processor Preparedness

In the event of a dairy-related crisis, the U.S. dairy industry will need to communicate efficiently and effectively to preserve and protect public confidence in dairy products. In an effort to help further its ongoing crisis preparedness effort, DMI has created a [Crisis Preparedness Toolkit](#) specifically for dairy processing companies. If your company already has a crisis communications plan, these tools will help you enhance it and if you don't have one yet, it will be the starting point for creating one.

The Crisis Preparedness Toolkit was created to:

1. Provide a template that will help you develop or expand your company's crisis plan
2. Help your company prepare for public perception crises related to your product
3. Further the dairy industry's overall crisis preparedness by uniting the industry with complementary plans.

These materials are focused on a communications response, but will likely be useful in developing operational response plans as well.

Additional resources for processors available on this site:

- [Dairy Industry Product Contamination Response Toolkit](#)
- [Roles and Responsibilities in a Crisis for Dairy Processors and Ingredient Suppliers](#)
- [Quality and Safety Initiative for U.S. Dairy Ingredients](#)

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## DAIRY NEWS



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 **DME** DAIRY MANAGEMENT INC.™

 **IDFA** International Dairy Foods Association  
Milk Industry Foundation  
National Cheese Institute  
International Ice Cream Association

 **MilkPEP**  
Milk Processor Education Program

 **nmpf** NATIONAL MILK  
PRODUCERS FEDERATION

 **USA** U.S. Dairy  
Export Council.

### Product Safety Details

We understand that you may be concerned about the quality of the milk your family drinks and the dairy products they eat. The latest Food and Drug Administration (FDA) announcement confirms that milk and dairy products are safe.

U.S. dairy products are among the most tested and regulated foods in the country and American dairy products are among the safest in the world. You can be confident in the continued safety of dairy products because of the strong network of safeguards already in place. If you have additional questions regarding product safety, please feel free to submit a question or visit the Frequently Asked Questions (FAQ) area of this Web site.

### A message from America's dairy farmers and processors:

Be assured that the dairy products you buy for your family continue to be safe, wholesome and pure. From the farm to the processing plant to your local grocery store, the dairy industry is working in concert with the U.S. Department of Agriculture (USDA) and the FDA to ensure the safety and quality of dairy products made in the United States.

The dairy industry is responding to the current situation with the utmost diligence and rigorous measures available to us. Our industry works closely with government agencies to maintain safe food. The U.S. government has expertise in regulating the manufacture and distribution of safe and healthy food. Our country leads the world in these capabilities.

### Links

To learn more about the situation and how the government is responding, we encourage you to visit the following Web sites for the latest information:

### LATEST INFORMATION

[News Updates](#)

[Product Information](#)

October 10, 2007

[There are no product recalls at this time](#)



# Social Media – A Challenge to Manage

facebook



twitter



You Tube



# DMI Social Media Monitoring

## Intensified Social Media Monitoring

We monitor for dairy issues on more than 225 sites within the Web, blog, and social media venues including more than:

- 130 individual websites and blogs
- 60 Twitter handles
- 25 Facebook pages
- 10 YouTube channels

*Plus key word searches*



## The New Goal for Crisis Response

**Begin responding  
via social media in  
*30 minutes or less***



# DMI Social Media Recommendations

## Advocate Actions

- **In advance of a crisis we encourage you to:**
  - Follow Latest Dairy News on Twitter: @latestdairynews
  - Establish and engage in social media properties
  - Identify advocates and partners
  - Plan how to utilize industry tools in a crisis



# DMI Social Media Recommendations

## Advocate Actions

- **In a crisis we encourage you to:**
  - Friend Latest Dairy News: [facebook.com/latestdairynews](https://www.facebook.com/latestdairynews)
  - Post industry statements
  - Post widgets
  - Use sample Tweets and Facebook updates





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# Questions/Discussion

# Matt Mathison Contact Information

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