

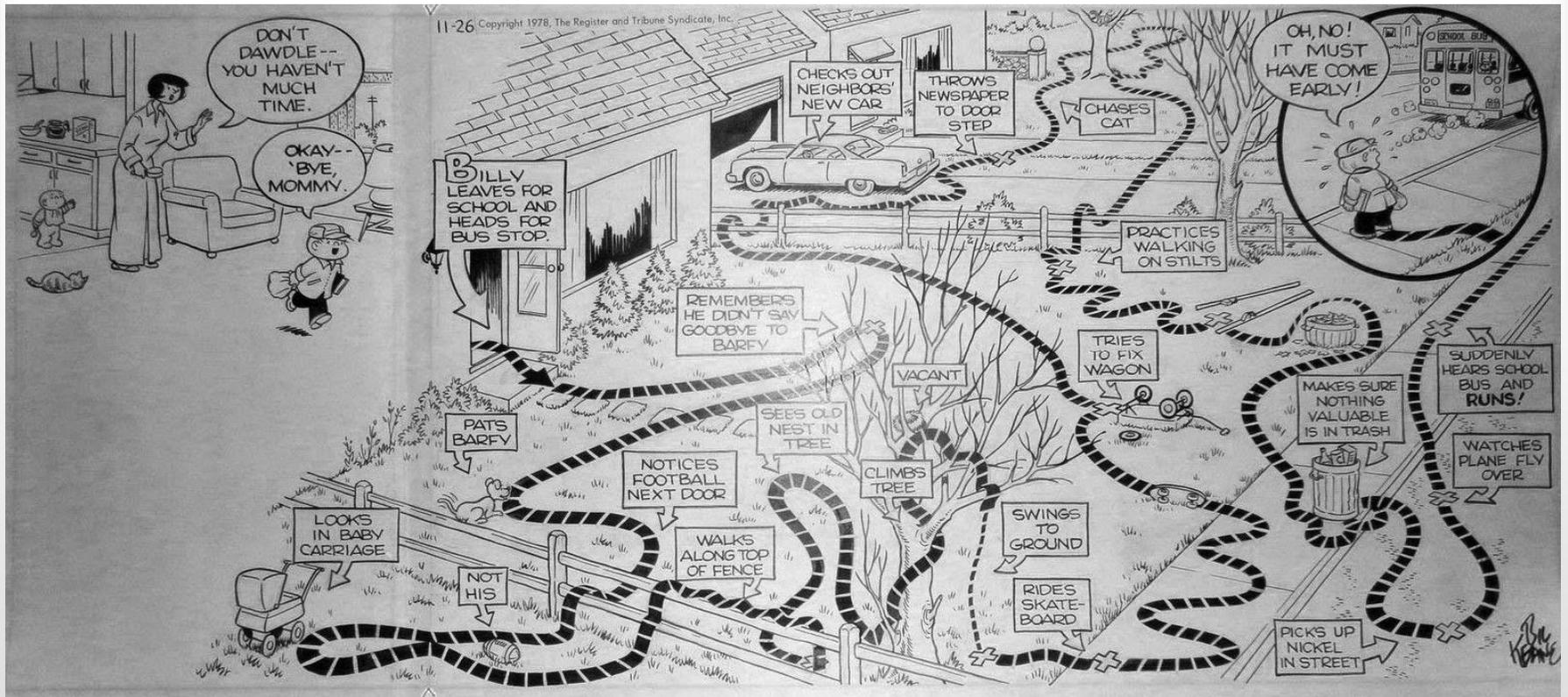
Food Product Recall: Company Response, Recovery and Restart

Joseph D. Meyer
VP, Quality & Food Safety
Miniat Holdings LLC

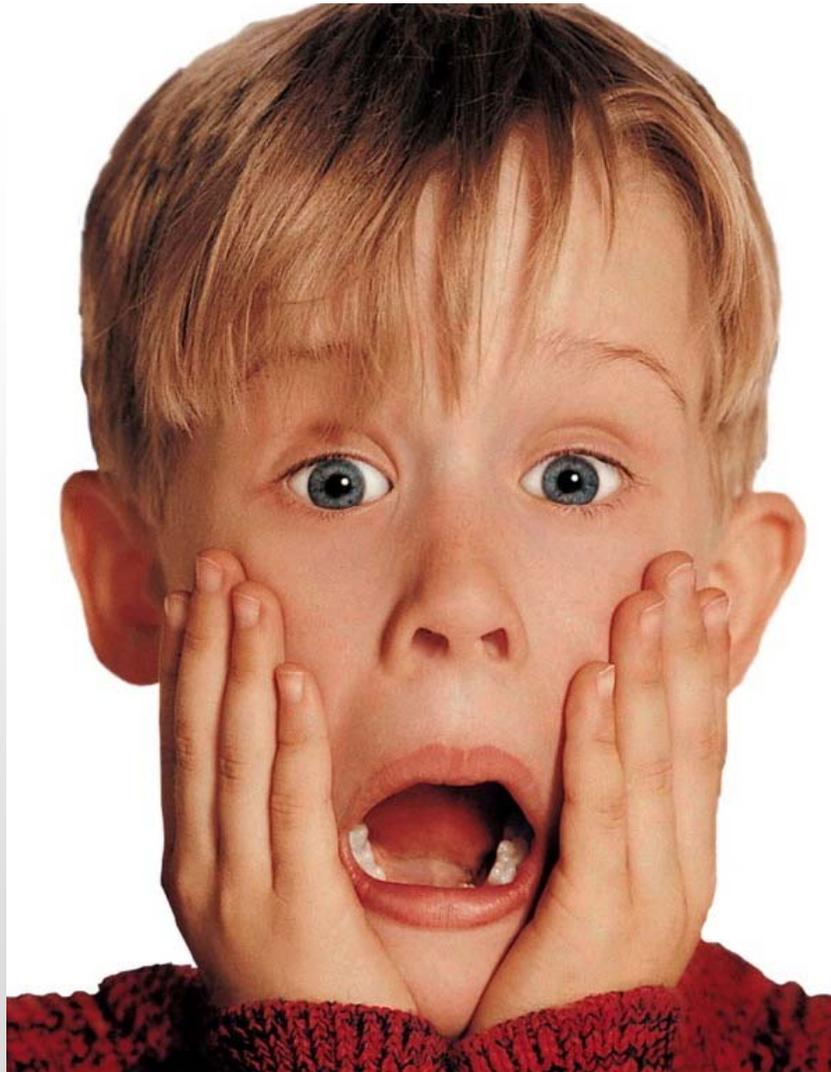
Overview

- **Response**
 - Team/stakeholders
 - Getting organized
 - Developing (implementing) the plan
- **Recovery**
 - Staying organized
 - Taking the next steps
 - Other considerations
- **Restart**
 - Verifying and sustaining
 - Getting back to “normal” or the “new normal”
 - Culture change (lessons learned)

Focus! Don't Miss the Bus!



Company Response



Team/Stakeholders

- **Corporate team**
- **Plant team**
- **Support team**
- **Other stakeholders**
 - **Regulators (local/state/district/national)**
 - **Public health (local/state/national)**
 - **Consumers**
 - **Customers**
 - **Employees**
 - **Media**

Team/Stakeholders

- **Corporate team needs to...**
 - Manage and direct resources, communications, decision making process
 - Keep process moving and on track
 - Coordinate with senior management, regulators, public health agencies
- **Plant team needs to...**
 - Investigate and fact check
 - Take action, implement plans
 - Provide feedback

Team/Stakeholders

- **Support team needs to...**
 - **Provide additional resources and technical expertise**
 - **Coordinate with external resources**
 - labs, suppliers, consultants, academia, trade associations, contractors
 - **Coordinate consumer/customer/employee/media activities and communication**
 - Website, FAQs, media requests
 - 800 number and required infrastructure
 - Medical support
 - Product recovery (and replenishment)
 - **Train team/stakeholders**
 - All involved may need to be educated on issue/organism/illness, the manufacturing process and control programs

Team/Stakeholders

- **Consultants**
 - Advise, recommend, guide, educate
 - Experience and technical “know how”
 - Network within food industry, academia, trade associations, regulatory agencies, public health agencies
 - Too many cooks spoil the broth
 - Multiple “right” approaches
 - You have to live with the result, they don’t
 - Bottom line, you are the one who is accountable (and will be held accountable)
 - You owe it to yourself to ensure you understand what you are doing and why
 - Make sure you own the decisions
 - Make sure you can carry on after the consultant is gone

Getting Organized

- **Set up a work space for each team**
 - Access to phone, computer, flip charts, other suppliers as needed
 - Sufficient space for meetings and conference calls
- **Develop and maintain a timeline**
 - Leading up to identification of the issue
 - Extending through investigation and recovery
- **Maintain an action register**
- **Daily status meeting**
 - Internal stakeholders
 - External stakeholders

The Response Plan

- **Hopefully, you are starting with an established recall plan that has been tested through a number of mock recall scenarios**
- **What initiated the situation?**
 - **Internal info, lab result, customer test, supplier info, regulatory inspection/sample, outbreak investigation, etc.**
 - **All could have different starting points and rates of escalation**
- **Need the team assembled and brought up to speed on available information**

The Response Plan

- **Need to answer the question of scope...**
 - Impact of the issue (i.e. allergen Vs pathogen)
 - Product, process, packaging
 - Product lot coding
 - Equipment
 - Cleaning and sanitation practices
 - Traffic patterns
 - Employees practices
 - Available documentation and data
- **What about other products or production lines?**

The Response Plan

- **Get facts, not opinions, and verify**
 - Everybody “knows” how process/rework/cleaning/etc. is “supposed” to work (but what is really happening)
 - Don’t use any rework (oh, except for that Canadian product we make twice a year and just happened to make that day)
- **Get it right the first time**
 - Multiple recalls don’t help anybody
- **Timeliness is important but...**
 - Need senior management, regulators, public health all on the same page
 - Consistent engagement and communication important
- **Goal is to remove the right product from the market place as quickly and effectively as possible**

The Response Plan

Think about who will respond to the media and get proper training...

“We're sorry for the massive disruption it's caused their lives. There's no one who wants this over more than I do. I would like my life back.”

BP CEO Tony Hayward, on the oil spill disaster that claimed 11 lives and spewed 20 to 100 million gallons of oil into the Gulf of Mexico, May 31, 2010

“Tragically, our products have been linked to illness and loss of life. To those people who are ill, and to the families who have lost loved ones, I offer my deepest and sincerest sympathies. Words cannot begin to express our sadness for their pain.”

Maple Leaf Foods President/CEO Michael McCain, on the 2008 listeriosis outbreak in Canada that claimed 21 lives with 56 confirmed cases.

Recovery

- **Recall itself is likely to just be the beginning of the process**
- **Ongoing team effort to continue investigation, take appropriate actions and ultimately resume production**
- **Biased approach based on the issue**
 - Allergen Vs pathogen
 - Internal plant driven Vs supplier driven
- **May require changes to products, process, equipment, procedures, programs, infrastructure, and/or culture**
- **Goal is to identify and correct root cause that created the issue**
 - What if you don't find the root cause?

Staying Organized

- **Continue to maintain a timeline**
- **Continue to maintain an action register**
- **Documentation and tracking**
 - Procedures, even temporary procedures
 - Sampling plans, samples, results
 - Training
- **Daily status meeting**
 - Internal stakeholders
 - External stakeholders (as needed)

Recovery Steps

- **How do you convince yourself, and most likely regulators, that you are ready to resume operations?**

Recovery Steps

- **Review all information, findings, data, etc.**
- **Conduct a gap analysis of the root cause against actions to be taken, updated procedures, etc.**
- **Develop a plan to demonstrate how you will address the root cause and take any additional steps needed to restore the operation**
 - Use previous industry learnings, when applicable
 - Get buy-in on plan before execution (senior management, regulators, etc.)
- **Determine how you will verify the effectiveness of actions taken, updated procedures, etc.**

Recovery Steps

- **Clear the plant for production**
 - Start-up sampling plan
 - Establish go/no-go criteria
 - Ramp up plan to full production
- **Replacement of stock in the market place**

Recovery Steps

- **No plan is perfect (always need a Plan B)**
- **Make sure any changes are fully communicated and have buy-in**
- **Complete verification of effectiveness**
- **Have you proven to yourself that you are manufacturing safe product?**

Other Considerations

- **Protecting other products and areas of the plant throughout the investigation**
- **Short term Vs long term strategy**
 - Capital improvements
 - Research initiatives
- **Use of contractors or temporary employees**
- **Additional third party services**
- **How to meet customers needs**
 - Alternative product, process or plant
 - Co-manufacturer

Restart and Beyond

- **How do I keep this from ever happening to me again?**
- **Don't kid yourself, there are no guarantees**
 - It is important that senior management truly understands this
 - You need an ongoing commitment from senior management and employees at all levels
- **How do you maintain interest and momentum in continuous improvement?**
 - Easy in the heat of the battle
 - Not as easy down the road

Verifying and Sustaining

- Heightened level of monitoring and verification activities for some period
- Challenge the system to see if it holds up
- Revisit each finding and action taken
- Review other products and production lines
- Follow through on long term strategy

Return to Normal (New Normal)

- **Sooner or later you need to return to normal (or a new normal) level of operation**
- **Need to develop a plan for de-escalation**
 - Phased approach
 - Milestones with go/no-go criteria
 - Periodic revisit of potential trouble spots
- **Stakeholder involvement and communication is just as important at this stage**
 - No surprises
 - Need everyone's engagement and support

Culture Change/Lessons Learned

- **Internalize learnings within company culture**
 - What role will food safety play in your culture?
- **Fill gaps identified in the recall plan and other programs during this issue**
- **Review the recall with all levels of staff**
 - The issue, findings, results, corrective actions
- **Develop a mechanism for ongoing sharing and education**
 - Close calls/near misses
 - Other industry issues (learn from others)
- **Maintain (and expand) network of contacts gained through recall**

Culture Change/Lessons Learned

- **Early warning system**
- **Know your history**
 - Polar Bar (no illnesses) – Blue Bell
 - Australian PB – Peter Pan – PCA – Sundland
- **Find problem when it is small, before it gets big**
 - Aggressive sampling will find more positives as you get closer to the source (more is good)
 - Can't fix it if you don't know the problem exists
- **No man (or company) is an island**
 - Be aware of what is happening within your industry
 - Share with, and learn from, your network of peers, universities, professional societies, trade orgs, etc.

Culture Change/Lesson Learned

- **Scientific advisory boards**
 - **What is the objective/goal/vision**
 - **Need to lay down the ground rules**
 - **When will they meet**
 - **Who engages with them**
 - **How you will use them**
 - **How you will respond to their advice and recommendations**
 - **Take time to select the right mix of fields and individuals to achieve the objective/goal/vision**
 - **Educate them on your category, products, processes, equipment, control programs, etc.**
 - **Field trips and plant tours**

Summary

- **Surviving a recall and coming out the other side a stronger company is a difficult task**
- **Preplanning is extremely important**
- **Each situation is going to be unique**
- **Stay organized and focused**
- **Learn from it and share the learnings broadly**

Resources

- **FDA**
 - <http://www.fda.gov/Safety/Recalls/IndustryGuidance/>
 - <http://www.fda.gov/Safety/Recalls/default.htm>
- **USDA**
 - <http://www.fsis.usda.gov/wps/wcm/connect/f00d2ba8-02ee-4b1f-9069-bb41f223aa88/8080.1.pdf?MOD=AJPERES>
 - <http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/current-recalls-and-alerts>
- **CFIA**
 - <http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/manufacturers-guide/eng/1376326890597/1376327095576>
 - <http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recall-warnings/eng/1299076382077/1299076493846>

Resources

- **DATCP**
 - http://datcp.wi.gov/Food/Food_Recalls/
- **GMA**
 - http://www.gmaonline.org/downloads/research-and-reports/WP_RecallExecution.pdf
- **University of Florida Extension**
 - <http://edis.ifas.ufl.edu/pdf/files/fs/fs10800.pdf>

Thank You!

~~UNPREPARED~~

