

MASSIVE ICE CREAM RECALL

Cause Map

Use of genome sequencing determines products have been contaminated with Listeria since 2010

At least ten people have been sickened, with three resulting deaths, due to an outbreak of Listeria in ice cream. Genome sequencing has linked the contaminant to cases of food-borne illness since 2010. As a result, 8 million gallons of ice cream have been disposed of, and all production lines were shut down.

"We're committed to doing the 100 percent right thing, and the best way to do that is to take all of our products off the market until we can be confident that they are all safe. At this point, we cannot say with certainty how Listeria was introduced to our facilities and so we have taken this unprecedented step. We continue to work with our team of experts to eliminate this problem."

- Paul Kruse, Blue Bell CEO and president

1 Problem

| | | |
|--------------|----------------------------|--|
| What | Problem(s) | Listeria outbreak |
| When | Date | Contamination believed to have begun in 2010 |
| | Time | N/A |
| | Different, unusual, unique | Use of genome sequencing; Listeria replicates in refrigerated temperatures |
| Where | Facility, site | All manufacturing plants |
| | Unit, area, equipment | All ice cream products |
| | Task being performed | Discovered during random sampling |

Impact to the Goals

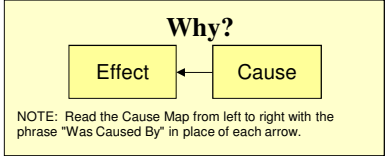
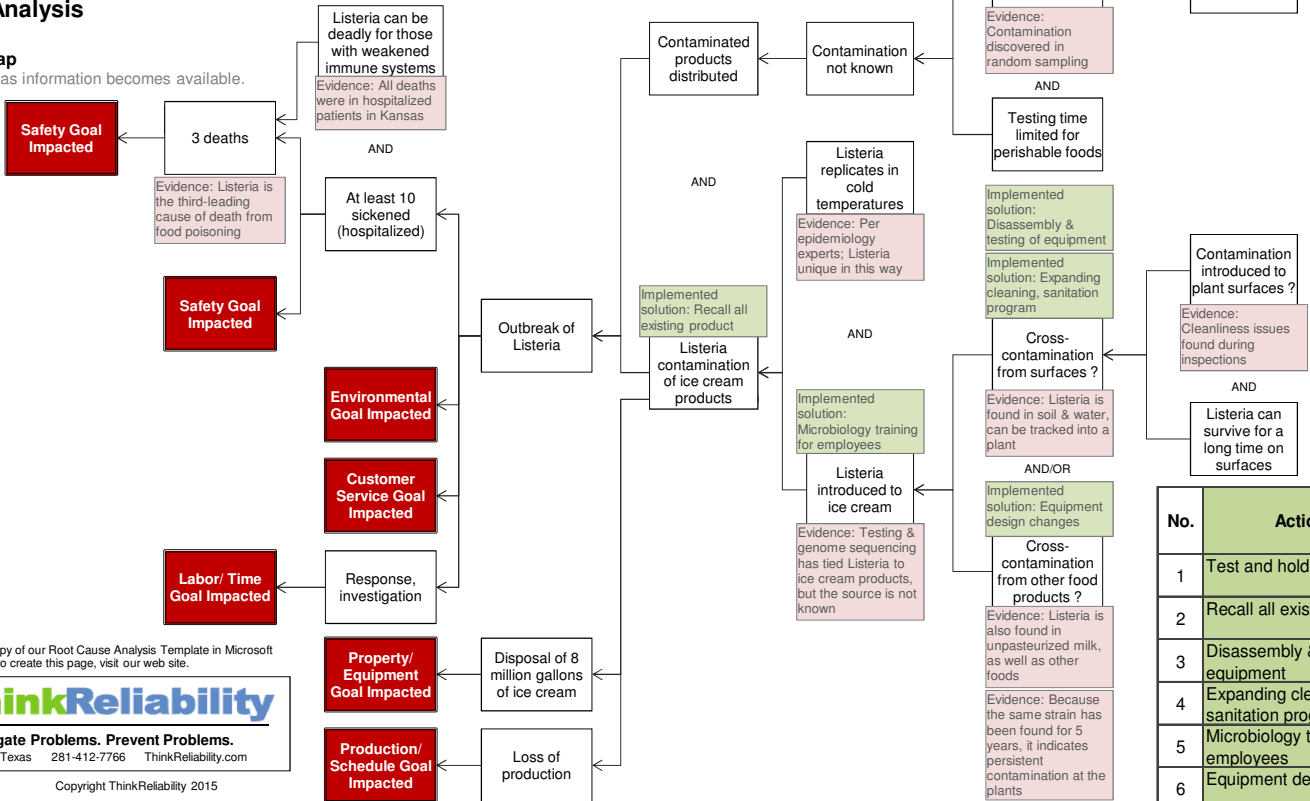
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|-----------------------------|---|
| Safety | 3 deaths At least 10 sickened (hospitalized) |
| Environmental | Outbreak of Listeria |
| Customer Service | |
| Regulatory | ? |
| Production/ Schedule | Loss of production |
| Property/ Equipment | Disposal of 8 million gallons of ice cream |
| Labor/ Time | Response, investigation |

Frequency
First recall in company's 108-year history; about 1600 Americans sickened by Listeria every year

2 Analysis

Cause Map

Add detail as information becomes available.



NOTE: Read the Cause Map from left to right with the phrase "Was Caused By" in place of each arrow.

Cause Mapping is a Root Cause Analysis method that captures basic cause-and-effect relationships supported with evidence.

CAUSE MAPPING

Problem Solving • Incident Investigation • Root Cause Analysis

Step 1 Problem What's the Problem?

Step 2 Analysis Why did it happen?

Step 3 Solutions What will be done?

3 Solutions

| No. | Action Item | Cause | Status |
|-----|--|--|------------------------------------|
| 1 | Test and hold process | Ice cream not tested for Listeria | Working with lab on implementation |
| 2 | Recall all existing product | Listeria contamination of ice cream products | Recall announced April 20 |
| 3 | Disassembly & testing of equipment | Cross-contamination from surfaces ? | Implemented April 27 |
| 4 | Expanding cleaning, sanitation program | | Implemented April 27 |
| 5 | Microbiology training for employees | Listeria introduced to ice cream | Implemented April 27 |
| 6 | Equipment design changes | Cross-contamination from other food products ? | ? |

For a free copy of our Root Cause Analysis Template in Microsoft Excel, used to create this page, visit our web site.

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