

Step 1. Outline

What	Problem(s)	Tampons infected with bacterial contamination
When	Date	November 9, 2011 (for products shipped October 29 - November 2, 2011)
Where	Different, unusual, unique	Manufactured with contaminated raw material
	State, city	Iowa, Kansas, Missouri, Nebraska, New Mexico, Texas, Arizona, Utah
	Facility, site	Walmart, Fry's, Smith's
	Contaminant	Enterobacter sakazakii
	Affected Product	Kotex Natural Balance Security Unscented Tampons Regular Absorbency

**Bacterial Contamination of Tampons
November 9, 2011**

On November 9, 2011, the FDA announced a recall of a certain subset of tampons for contamination with the bacteria Enterobacter sakazakii. The recall is for certain products delivered to certain stores, mainly in the central U.S. Region. For a full list of the product recalls, check the FDA recall site.

The specific source of the contaminant has not been identified. Investigations of previous instances of contamination with the Enterobacter sakazakii have had difficulty determining an exact source, as this bacteria is found within human and animal guts. However, even with limited information, we can begin a Cause Map, or visual root cause analysis, which allows us to view the areas where more data collection is needed in order to gather evidence to complete the analysis.

We begin by capturing the basic information about the incident as well as the impacts to the goals. The safety goal is impacted due to the risk of infection from the contamination tampons. The environmental and customer service goals are impacted because a product was bacterially contaminated. Additionally, the product recall impacts the production, property and labor goals. We begin our Cause Map with the impacts to the goals.

Impact to the Goals

Safety	Risk for infection	?
Environmental	Bacterial contamination of product	
Customer Service		
Production-Schedule		
Property, Equip, Mtls	Recall of product	
Labor, Time		
Frequency	Rare	
	Annualized Cost	?

Both the risk for infection and the product recall were caused by the bacterial contamination of a product. The product was contaminated because contaminated raw material was used for its manufacture. This occurred both because the raw material was contaminated and because the quality control or testing process for the raw material was insufficient. Whether there was no testing process for the given bacteria or whether the process did not recognize the bacteria and stop the use of the contaminated raw material is unclear.

At this point, because the source of the raw material contamination is unknown, an open question which requires evidence-gathering is "how did the raw material get contaminated"? This will require cooperation from the raw material manufacturer. The other necessary information is to do a detailed review of the quality control and/or testing that is used on raw materials prior to manufacturing and determine how the contaminated material was able to be used to make a final product. Once this process is looked at in detail, specific solutions that would prevent a recurrence of this type of contamination can be implemented.

