

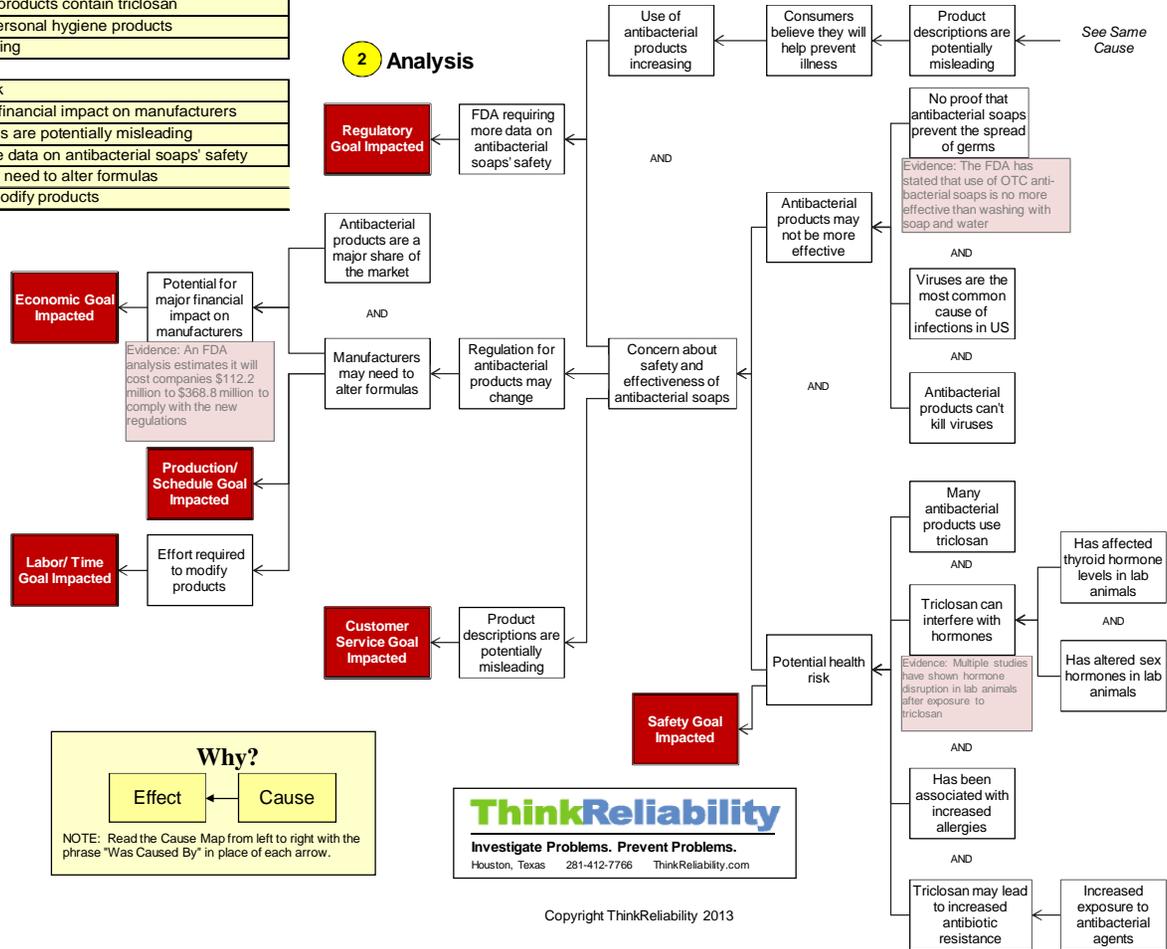
FDA Ruling Questions Safety and Effectiveness of Antibacterial Soaps

1 Problem

What	Problem(s)	Concerns over the safety and effectiveness of antibacterial soaps
When	Date	New FDA ruling December 16, 2013
	Different, unusual, unique	Many antibacterial products contain triclosan
Where	Facility, site	Ruling applies to personal hygiene products
	Task being performed	Cleaning and washing
Impact to the Goals		
Safety		Potential health risk
Economic		Potential for major financial impact on manufacturers
Customer Service		Product descriptions are potentially misleading
Regulatory		FDA requiring more data on antibacterial soaps' safety
Production/ Schedule		Manufacturers may need to alter formulas
Labor/ Time		Effort required to modify products

The Federal Drug Agency (FDA) has formally questioned the safety and effectiveness of antibacterial soaps with a ruling on December 16, 2013. Manufacturers of antibacterial soaps have one year to provide data that proves that anti-bacterial soaps are both safe and more effective than regular soap and water.

2 Analysis



3 Solutions

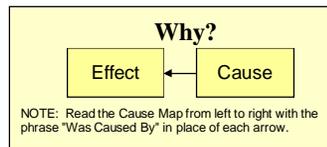
The final step in the Cause Mapping process is to provide solutions that prevent the issue from recurring. In this example, the FDA is gathering more information to determine if antibacterial handsoaps are safe and effective. Any antibacterial products that have not provided sufficient data to satisfy regulators by late 2016 would have to be reformulated, relabeled or removed from the market.

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?



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