Case study

Regulatory roadblock

FDA suspends peanut butter plant due to E. coli outbreak

All domestic and foreign companies that manufacture, process or pack food for consumption in the US must have their registration renewed with the Department of Human Health and Services (HSS) every two years. This is mandated under the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA). The FDA now has the power under FSMA to suspend the registration of a facility if the agency determines food has a reasonable probability of causing death or other serious harm to animals or humans.

In this case study, we explore how a peanut butter manufacturer had their facility suspended due to an E. coli outbreak, which resulted in a total halt on production and a ban on selling food interstate.

Investigation and testing

A privately-owned peanut butter manufacturer* established over 15 years ago generates over USD 17,000,000 in sales. USD 12,000,000 of this comes from peanut butter manufactured fortheir retailers' own labels.

The FDA inspected the manufacturer's premises as part of their registration process and the inspection revealed unsanitary conditions which could affect the safety of the peanut butter. As a result, the manufacturer was issued with a Suspension of Food Facility Registration Order which meant no food could leave the premises. At this stage the business elected not to recall the peanut butter, which had already been distributed to retailers to be sold under their own labels.

The manufacturer had previously conducted comprehensive environmental testing and had a control process in place which had not shown any positive test results for E. coli. The FDA presented their positive E. coli test findings and the company undertook a thorough investigation of cause of the E. coli outbreak, which involved bringing in experts and engaging with external laboratories. In conjunction with the investigation, the manufacturer rented a storage facility next to their factory to isolate the product that had been tested and returned negative results for the pathogen.

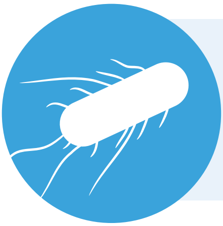
After much investigation, **the source of the outbreak was identified as being insufficient cleaning of a small rubber seal** between production runs, due to an employee not following the clean down procedure. ▶

Did you know?

The FDA reports that roughly one in six Americans get sick, while 3,000 die, each year from foodborne illnesses.

▶ To resolve the issue the manufacturer replaced the seal and re-ran environmental swabs at this critical control point between production runs.

Despite the problem being rectified, a significant clean-up effort was now needed to ensure no E. coli was present elsewhere within the plant. This involved hiring a specialist firm to deep clean, undertaking of a programme of retesting at the facility, obtaining independent third party lab results and producing a full update on findings to satisfy the FDA that the plant was safe to start manufacturing peanut butter again.



$342,900

Total amount the business lost over 6 days

Estimating the loss

The suspension order meant that the business lost six days production, at an overall cost of USD 57,150 a day, equating to USD 342,900 in total. In addition, one of their retail customers heard about their issue and pulled all of the manufacturer's peanut butter from their shelves. Given the relatively long shelf life, they had taken receipt of half their contract value to the amount of USD 900,000. All of this product was returned at a cost to the retailer. The retailer also submitted USD 45,000 of unsubstantiated costs to remove product from their five retail outlets. The expert clean down of the plant cost the business USD 72,500 and involved overtime payable to employees of USD 7,500. Given the size of the firm, these costs effectively wiped out any profits for the next two quarters and put a strain on the cash flow of the business.

The manufacturer did not have sufficient cash reserves to satisfy even a third of these claims, especially as they needed to purchase raw materials to continue operating and fulfilling other orders. Additionally, three customers filed lawsuits and the manufacturer's in-house lawyer required the help of external counsel who charged USD 450 per hour and required a USD 20,000 retainer.

How the policy works

As a result of the plant suspension, **the manufacturer's financial loss was two-fold, their own and the costs they incurred from their retail customer.**

The manufacturer had elected to purchase CFC's plant suspension trigger under the policy which covers their recall costs, and full third party recall costs. In addition the clean down was picked up under the plant rectification section of the policy, the unsubstantiated retail costs was picked up under the retailer's costs section of the policy.

> By purchasing the government plant suspension extension the company ensured the survival of their business and safeguarded their cash flow.

By purchasing the government plant suspension extension the company ensured the survival of their business and safeguarded their cash flow. This foresight meant the manufacturer had sufficient means to resume manufacturing as quickly as possible and by demonstrating a quick resolution for their retail customer, in turn they retained their business critical retail contracts going forward.

** The companies and circumstances in this case study are fictional, but the scenarios are realistic and reasonable based on our experience.*