Can Seam Integrity and Food Safety - Implications for Industry

Laboratories & Consulting Group

Overview

- The scope of the presentation is limited to leakage-related spoilage in metal cans
- History of can leakage related food safety concerns
- The impact of the FDA's investigation of New Era Canning Co. – the rest of the story
- Recommendations for the investigation of apparent leakage-related spoilage

A Common Scenario

- You process 60,000 cans of a low-acid product through a hydrostatic cooker on each of 3 consecutive days and bright stack the cans for later labeling and shipment.
- On the first day of processing, the can cooling water had an acceptable free chlorine residual and an Aerobic Plate Count of 500 cfu/ml; on the second day of processing the cooling water counts had risen to 2,200 cfu/ml; by the third day of processing the cooling water counts were up to 58,000 cfu/ml and there was no residual chlorine in one three daily checks.
- Ten days after processing, the cans were de-palletized for inspection and labeling. There were 3 swells/low vacuum cans from Day 1; 5 such cans from Day 2 and 12 such cans from Day 3.
- Representative cans from each day were tested, but not cultured: in all tested cans, the pH was 0.4 units lower; long thin rod-shaped bacteria were seen on product smears; can seams were within specification, but some seams were slightly loose. No seam failed a dye test.

History of Can Leakage Spoilage

- The history LACF leaker spoilage and public health issues is largely unremarkable.
  - **The 1981 Alaskan canned salmon botulism incident.** In a strict sense, this was leaker spoilage although it was atypical in that cans had a visible square hole near the seam caused by the can expansion and seaming equipment. Also, the cans were cooled in an environment that one would expect to have relatively high numbers of *Clostridium botulinum*.
  - There have been numerous incidents of finding mesophilic anaerobes in cans with apparent leaker-related spoilage, but often these organisms were not further identified and cans were simply never shipped and were destroyed or recalled. These incidents are in FDA's collective memory.
  - In the early 1980s, an industry study that looked at can cooling water in retort systems cultured water samples for anaerobic spores and identified all of the suspect organisms – no *C. botulinum* was found out of hundreds of samples.
  - The above facts and incidents created a collective belief within FDA that can leaker spoilage was unlikely to be a risk of botulism, but this risk was NOT ZERO.

New Era and Leaker Spoilage

- The FDA had just come off of the 2007 Castleberry botulism incident – a case of under-processing related to crate-less retort operation? The FDA was determined to re-invigorate its scrutiny of the LACF industry.
- FDA went to New Era on an assignment to look at the 30 or so US firms that operated similar crate-less retorts. Once in New Era, the focus soon turned to the operation of its FMC rotary cooker. This was driven by the finding of large numbers of swollen and leaking cans in the warehouse, some of which were 3 or more years old.
- The investigation was conducted in the winter in between blizzards with up to 30 FDA investigators on site at one time. Observations led to the opening of a criminal investigation that ran in parallel with the spoilage investigation.
- Swollen and flat #10 cans of green beans (along with other products) were transported to FDA's Arkansas Regional Lab by FDA agents in a rented truck for fear the cans would explode if transported by air.

Findings from the New Era investigation

- Can spoilage issues stemmed from **poor seam**s – generally too loose with some short critical measurements combined with **rough can handling and a** small number of **cans that were not processed.** There were frequent jams, dropped cans, retort stoppages, and a failure to account for unprocessed cans in the retort infeed airlock.
- The criminal investigation began when investigators discovered that the company was using a purpose-built press to flatten "buckled" #10 cans of green beans, invert the cans to put the dents on the bottom, and then sell them to the California school lunch program.
- The Arkansas regional lab found that the cans had leaker-related spoilage. Interestingly, **the FDA lab isolated *C. botulinum* from FLAT cans of green beans.** No botulinum toxin could be detected in the cans. The cans had a pH of 4.9 – 5.0 and showed no obvious signs of spoilage.

Findings from the New Era investigation

- There is a history of *C. botulinum* growth in canned green beans without can swells – first documented in the 1930s. There have been botulism deaths from canned green beans in the past. The product pH is close to the limit for toxin production in foods (as opposed to lab media).
- Investigators noticed a "sink hole" near the 4 wells that supplied unchlorinated cooling water to the retorts. This sink hole was due to a fractured water pipe fed by several of the wells. Soil may have been aspirated into the cooling water.
- Cooling water samples were tested by CFSAN and by a private lab. Both labs found *C. botulinum* in the cooling water. The private lab ran counts and estimated approx. 10 cells/spores per ml.
- On the strength of this data, FDA encouraged the firm to conduct an extensive recall and required extensive destructive sampling of other products in the warehouse, some of which were more than 3 years old.

Outcomes of the New Era Investigation

- The owner was charged with a felony under the FFD&C Act, and later plead guilty to a reduced misdemeanor charge.
- The cannery was financially struggling before the FDA investigation and the cost of the recall, the shutdown, and legal fees necessitated the sale of the company to investors. It continues to operate today as Burnette Foods.
- Laboratory investigations continued – The *C. botulinum* strains were sent to CFSAN and the genome was sequenced and compared to the cooling water isolates – **the genomes were identical**. FDA published these studies in peer-reviewed scientific literature.
- Although New Era was a kind of perfect storm, it gave FDA more case history to enforce its concerns that leaker spoilage can be a potential public health risk and that such spoilage should be credibly investigated.

Back to Our Scenario

- Our swells and loss of vacuum looks **highly** typical of leaker spoilage – we even have a nice correlation of rate of defects to can cooling water micro counts. So what do we do with these three lots?
  - Day 1 – 1 defect in 20,000
  - Day 2 – 1 defect in 12,000 cans
  - Day 3 – 1 defect in 5,000
- FDA will tell you that there is no acceptable defect rate for *C. botulinum* in low acid canned foods. If you find a problem, you need to investigate the cans further to rule out a public health concern. **How you do this, is up to you**, but FDA may second guess you if they find your efforts to be insufficient.
- FDA has not issued any guidance on how to handle such investigations, nor are they likely to do so – there are many variables and considerations.

How Should You Investigate this Scenario?

- Each situation is unique – you must consider the product. Is it one like our green beans that will barely support the growth of *C. botulinum* or one that is known to support vigorous growth? Remember that carrot juice supported *C. botulinum* growth with huge amounts of toxin production with no swells and no sensory defect!
- At a minimum, all of the defective cans should be examined to some degree, as well as some apparently normal cans. Ask yourself if the cans have been held at a time and temperature that would allow for an organism like *C. botulinum* or other microorganisms to grow in the product. If not, consider incubating the cans before testing.
- Find a lab that knows how to do LACF spoilage testing properly – i.e., by the methods in the Compendium for the Microbiological Examination of Foods.

How Should You Investigate this Scenario?

- You will want to assess:
  - Perform can seam teardown with critical measurements.
  - Meta-data such as the weight of can contents, drained garnish weight, the production log, and cooling water aerobic plate counts may be useful.
  - Measure the pH of can contents, make a product smear of each can for microscopic eamination.
  - Test a reasonable number of the cans using the Compendium procedure for LACF spoilage investigation.
  - Run some of the normal cans through the same testing.
- The purpose of this is to make a credible effort to rule out the possibility of a mesophilic anaerobe being the cause of spoilage.
- In most cases, the can seam evaluation will be unremarkable – apparently normal can seams do "inhale" a small amount of can cooling water.

How Should You Investigate this Scenario?

- "Data is King" – be prepared to defend your decisions with data. However, we need not break the bank holding every lot of product while we fully test every defective can or incubate cans in a search for low defect rates – **but do something to collect data and document what you do.**
- In cases like our scenario, you can get by with investigating at least half of the spoiled cans and a few normal cans. A microscopic examination of the product can be very revealing – long thin rods without spores are typical of some lactic acid bacteria spoilage. If the product pH drops below 4.6, it may not be necessary to conduct a microbiological assessment, particularly if the product is not putrid and the product smear does not show spores or Clostridia-like rod shaped bacteria.
- The microbiological examination, combined with other tests will almost always give you definitive data to confirm leaker spoilage.

How Should You Investigate this Scenario?

- In chlorinated cooling water, spore-forming bacteria tend to survive better than vegetative bacteria. This means you can have leaker spoilage and find nothing but spore-formers in the product.
- In cases where leaker spoilage cannot be proved, it may be necessary to incubate some product and re-examine the incubated cans for spoilage. **How much should you incubate?**
  - The short answer is "as much as you can." However, if you have pallets of about 50 – 60 cases, if you incubate 3 cases per pallet, you will have about a 65% chance of finding a can defect rate of 1 in 10,000.
- How long should you incubate these cans and at what temperature?
  - You can usually detect leaker spoilage in 14 days or less. Consider going for 10 days @ 93°F or 7 days @ 102°F. At 90°F, you are close to the lower limit for "incubation" and you should go 14 days at that temperature.

The Bottom Line

- Zero defects is unattainable. Do trend analysis on your defect rate. This number will be affected by the retort system, product, can size and design, can handling system, and the cooling water quality. Set your own performance goals and do trend analysis.
- Pay attention to cooling water Aerobic Plate Counts.
- When you conduct an investigation of spoilage, use all of the expert resources available to you – can manufacturers, process authorities, and canned food microbiology experts.