Regulatory Aspects – Integrity of Food Containers

IFTPS Annual Meeting
Container Integrity and Spoilage Investigation
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Objectives

- FDA Compliance Policy on can seam defects
- FDA regulations and guidance on container integrity
- Considerations for minimizing the potential for leakage and contamination
- What FDA requires when spoilage, contamination or process deviations are found after shipment

FDA Compliance Policy Guide 520.200 Canned Foods – Seam defects

The Goal for Container Integrity under Part 113.60

- **Creation and maintenance of a hermetic seal**
- **Designed and intended to be secure against entry by microorganisms**

Primary Intent
21 CFR Part 113 Regarding control & Testing of can Seams

- **Prevent product adulteration due to leakage during cooling and handling after retorting**
- **Because can seam defects do not always lead to product adulteration, FDA cannot take action against products on can defects only**

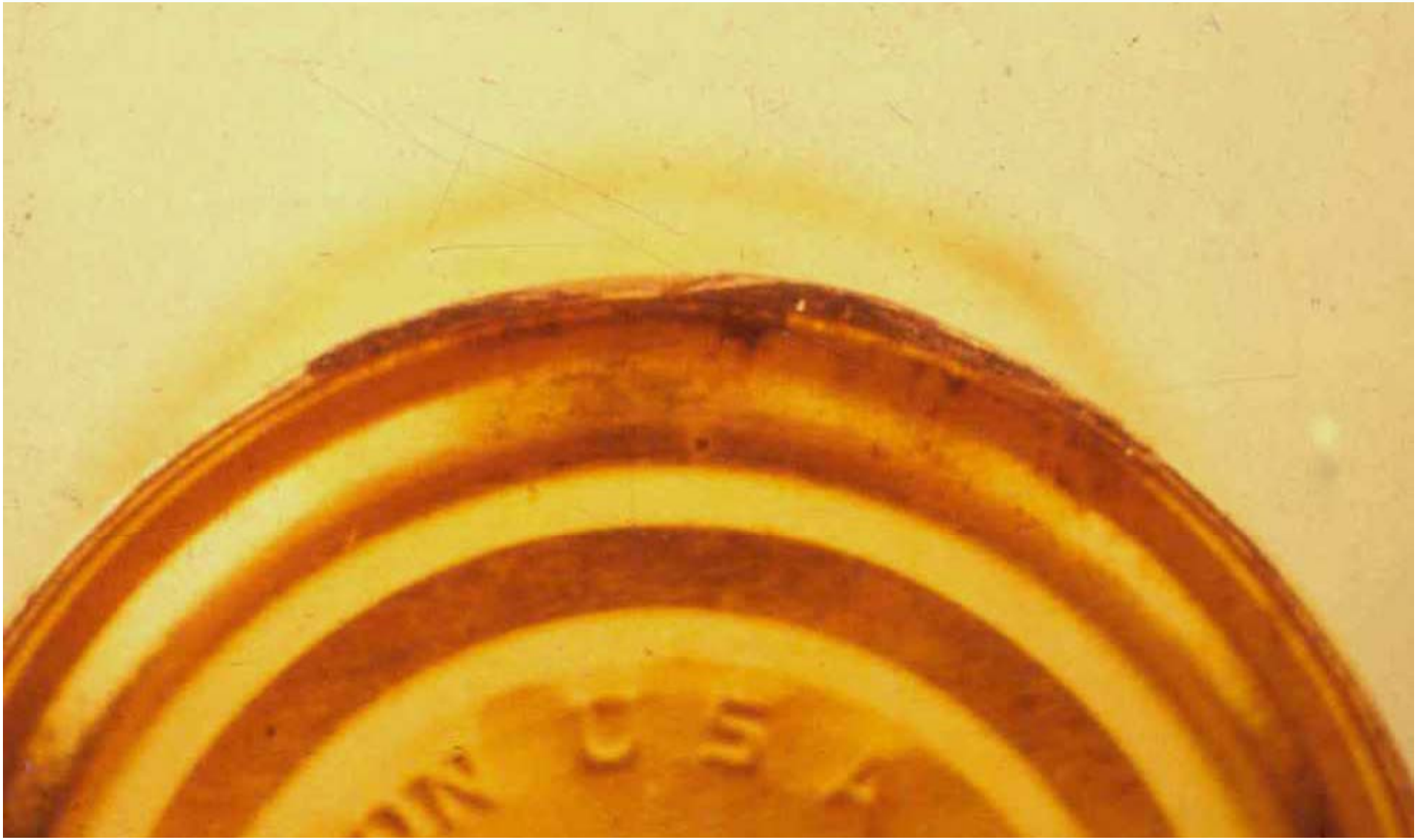
FDA Compliance Policy Guide 520.200

- For Legal action – there must be evidence of product adulteration
- Product adulteration includes the presence of viable microorganisms, filthy, putrid or decomposed substances, swollen, leaking containers

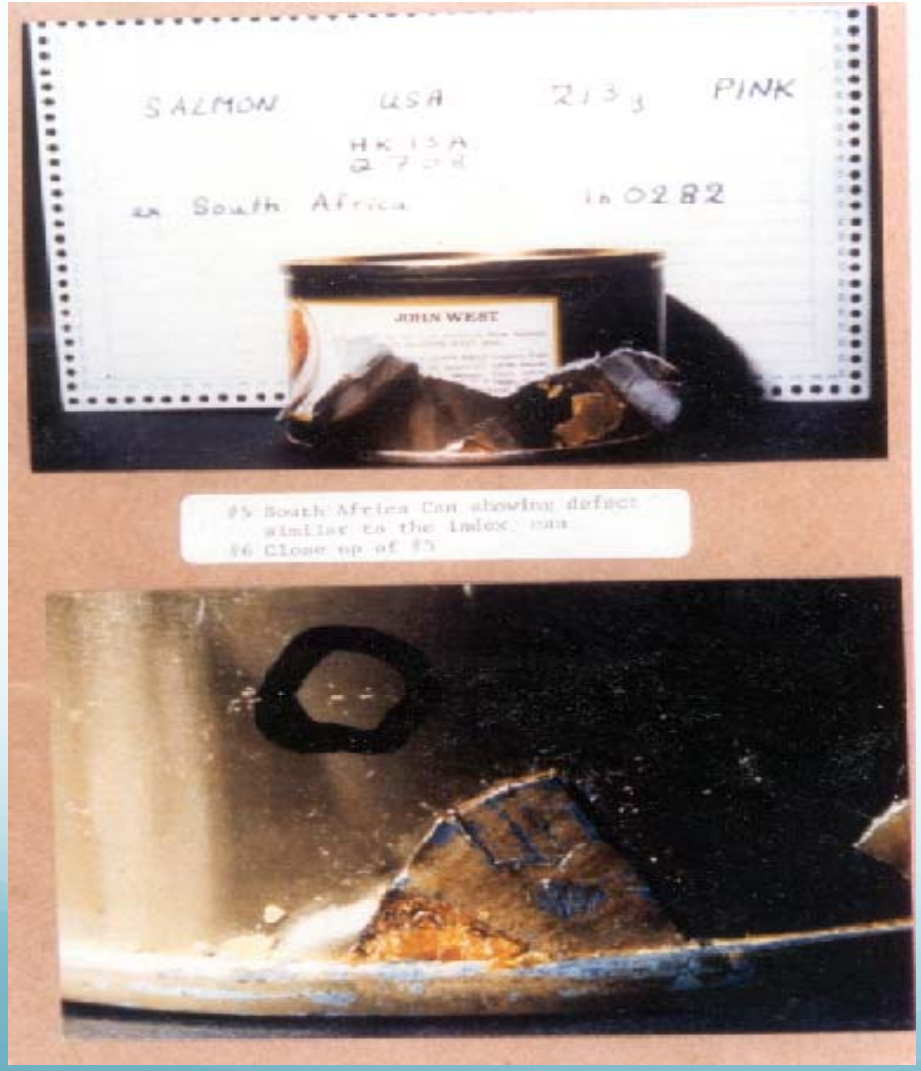
Probability of C bot Toxin in Canned Food due to Post Process Leakage:

- Rare and random event
- One case every 260 billion can consumed
- 10 -9 to 10-12
- One defective container can wreak huge economic damage on an entire industry.

1978 Canned Salmon Recall



1982 Canned Salmon Recall



AOAC Pictorial Posters Classifying Can Seam Defects

- AOAC Pictorial Poster for Metal Can Defects, 1984
- AOAC Pictorial Poster for Plastic Containers Defects, 1989
- Defects classified as critical, major and minor based on their propensity to leak

FDA Bacteriological Analytical Manual (BAM)

- **Chapter 21A – Examination of canned foods**
- **Chapter 22A – Integrity testing metal cans**
- **Chapter 22B - Integrity testing glass containers**
- **Chapter 22C - Integrity testing flexible/ semi- rigid containers**

http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm

FDA Regulations Covering Container Integrity

FDA Regulations Covering Low Acid Canned Food Container Integrity 21CFR Part 113.60(a)(1)(2)(3)

Part 113.60(a)

- **“Shall” visually Inspect the top seam of a can or closure of any other type of container at intervals of sufficient frequency**
- **“Should” inspect at least once every 30 minutes; for double seam cans – gross closure defects**
- **Regular and additional inspections “Shall” be made & pertinent observations recorded**

Part 113.60(a)(1)

- Tear down examination of double seam cans “Shall” be performed and recorded from enough cans from each seaming station at intervals of sufficient frequency
- Should be made at least once every 4 hours
- Computerized systems – valid entries and validation are concerns

113.60(a)(2)

- **Addresses Container Integrity for Glass Containers**
- **Cold Water Vacuum Test required for glass containers with vacuum closures; test results “Shall” be recorded**
- **Industry container tests – pull-up, security, visual tests before and after processing including vacuum, head space, sealing temperature and container condition (BAM Chapter 22B)**

113.60(a)(3) - Closures Other Than Double Seams and Glass

- **Appropriate and detailed inspections and tests shall be conducted and documented by qualified personnel at intervals of sufficient frequency**
- **To ensure proper closing machine performance and consistently reliable hermetic seal production**
- **Tests outlined in BAM, Chapter 22C**

Flexible and Semi-Rigid Containers

- Inadequate seal formation and container abuse during and after processing are concerns that can adversely affect container integrity
- GMA Bulletin 41L addresses acceptable integrity test procedures
- BPCS Manual, chapter 17, covers these containers

Cooling Water 113.60(b)

- **“Shall” be be chlorinated or otherwise sanitized as necessary for cooling canals and recirculated water supplies**
- **“Should” be a measurable residual at the water discharge end of the container cooler**

Single Pass Container Cooling Systems

- **Each plant shall be equipped with adequate sanitary facilities and accommodations (Part 110.37)**
- **The water supply shall be sufficient for the operations intended and shall be derived from an adequate source (Part 110.37)**

Post Process Handling 113.60(d)

- Can conveyors should be constructed so as to minimize contact by the belt with the double seam
- All worn and frayed belting, can retarders, cushions, etc. should be replaced with new nonporous material
- All tracks and belts that come into contact with cans seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency

Container Handling Equipment
(Amended Part 113.60(d))

- **Equipment used in handling filled containers Shall be designed, constructed and operated to preserve the can seam or other container integrity**
- **Automated & non-automated equipment Shall be checked with sufficient frequency and repaired or replaced as necessary to prevent damage to containers and container closures**

Acidified Foods 114.80(a)(40)

- Testing and examination of seams shall be performed often enough to protect the product from leakage and contamination

Aseptic Processing Concerns

- **LACFs, Acidified Foods, Acid Foods**
- **Avoid leakage and contamination!**

FDA Regulations - Aseptically Filled & Sealed Containers

- **113.40(g)(2)(a) – Container & closure sterilization system and product filling and closing system shall be instrumented to demonstrate that the required sterilization is being accomplished continuously.**
- **Automatic Recording Devices "Shall be used" – control sterilization media flow rates, temp. concentration & other critical factors**

FDA Regulations - Aseptically Filled & Sealed Containers

- **110. 80(b)(13) - Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination**
- **Compliance with this section: Identify and control critical factors –**
  - **Clean & sanitize food contact surfaces**
  - **Use safe & suitable packaging materials**
  - **Physical protection from contamination**
  - **Use sanitary handling procedures**

Preventing Post Process Leakage and Contamination:

- Validation of sterilization of packaging material, filling/sealing equipment and formation of the hermetic seal
- On going verification and assessment of packaging equipment & sterilization sterilization
- Change control procedures
- Good Documentation!!

Preventing Post Process Leakage and Contamination:

- Preventative Maintenance of Packaging Equipment – double seamers/bar sealers
- Training Seam Inspectors
- Proper Warehousing Procedures
- Proper Container handling pre and post process
- Proper sanitizing of container cooling water

WHAT IF SPOILED LOTS ARE SHIPPED?

Reportable Food Registry RFR

- **Covers all foods regulated by FDA except infant formula and dietary supplements.**
- **Requires a responsible party to file a report through the RFR electronic portal when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Such foods are "Reportable Foods."**
- **Reporting portal: www.safetyreporting.hhs.gov**
  - **(RFR MANDATED BY FDA Amendments Act of 2007)**

Emergency Permit Control Regulation Requirements
Part 108, Subpart B

- **LACFs - Shipped lots with any instance of spoilage or process deviation indicating potential public health significance – must inform FDA – 108.35(d)(e)**
- **Acidified Foods – Shipped lots with any instance of spoilage, process deviation or contamination with microorganisms of potential public health significance – must inform FDA – 108.25(d)**

Questions?