



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov



Acidified/Low Acid Canned Foods Filing Update

IFTPS 2013 – San Antonio, Texas

Dan Geffin

Minal Lalpuria



Outline

- Top reasons for return
 - Acidified foods
 - Low acid canned foods
- Acidified Guidance status
- Questions



Top Reasons for Returns – AF

- **Non-descriptive product name**
 - simply thick, vegan sauce, dips, chutney, pâté, health drink, pickle, etc.



Instead, provide a descriptive name such as ...

- mustard sauce, pepper and onion sauce, mango chutney, green olive pâté, carrot banana and apple juice, aloe vera drink, etc.

OR provide ingredients in comments/attachment



Top Reasons for Returns – AF

- **Missing product style and/or packing medium**

- Cucumber pickle, whole capers, roasted eggplant, vegetable salad, etc.

Instead, product name should be...

- cucumber spears in brine, whole capers in vinegar, roasted egg plant rings in chili oil, carrots cauliflower beans pieces in vinegar brine, etc.



Top Reasons for Returns – AF

- **Cold fill hold**

No challenge study or support document

Inadequate challenge study

- missing ATR, missing critical factors, unclear results, etc.



Top Reasons for Returns – AF/LACF

- **Least Sterilization Value**
 - You don't know what LSV means
 - You don't enter an LSV
 - Your LSV exceeds the process delivered
 - Your LSV not adequate for the product
 - Your LSV is borderline, and you no thermo-bacterial authority supporting it



Top Reasons for Returns – LACF

- Dry Ingredients (beans, rice, pasta, etc....)

Minimum Percent Moisture before filling

OR

Formulation Control (Water/Dry Ingredient Ratio)

OR

Minimum Blanch/Hydration (Time and Temperature)

(Explain what fully hydrated is if you use the term)



Top Reasons for Returns – LACF

- Water Spray/Cascade/Immersion
 - No CUT Filed
 - CUT Filed but No TD Attached
 - TD Does Not Support CUT
 - No IT Given on Ballast
 - TD doesn't Start at t_0 **(No initial horizontal leg)**



Top Reasons for Returns – LACF

- Flexible/Semi Rigid Containers

Minimum Overpressure/Thickness

Residual Air

Racking Configuration (coffin, vertical orientation)



Top Reasons for Returns – LACF

- Steam Air

Agitation or HD Study

Fan RPM

Maximum Overpressure/Steam Air Ratio

Partial Loads?



ACIDIFIED GUIDANCE STATUS





U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov



Questions?



www.CartoonStock.com