# IFTPS HPP Symposium
# 2018 IFTPS Symposium – February 27, 2018
# HIGH PRESSURE PROCESSING
## PRODUCT CONCEPT TO COMMERCIAL PRODUCT

**Manufacturing Case Study**

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# AGENDA

## Manufacturing Case Study
## Clostridium Botulinum

- Brief Bios
- Synopsis
- What happened?
  - Clostridium Botulinum pertinent organism?
- Key Learnings
- Outcome and Proposal
- Summary

# Malcolm Knight

- B.Sc. & PhD Kings College, London University
- FIFST – Fellow Inst. Food Science and Technology
- Former Chairman European Chilled Food Assoc.
- Business start ups – investor and Executive SVP
- Oil and Energy - ADS sold to Expro
- Extensive Food and Beverage Career
  - Heinz VP Operations Europe & USA
  - SVP POM Wonderful, Fiji Water
  - Board member Pressed Juicery

# Jill Costelow

- B.S. Food Science, University of California, Davis.
- Original member writing FDA's Juice HACCP plan
- Extensive thermal and non- thermal processing background Aseptic - Hot/Cold Fill - HPP - PEF
- Certified BRC auditor, SQF, HACCP Trainer
- Extensive Food and Beverage Career
  - Nestle, Coca Cola, Frito Lay, Odwalla
  - Pressed Juicery, POM Wonderful, Calif Natural Products

# Synopsis

- Real Manufacturing Events in 2015-2016
- Routine Inspection
- *C. Botulinum* as pertinent organism
- Juice and non juice beverages, emphasis pH >4.6
- FDA Inspection over 2 week period
- Pertinent organism discussions (Plant, FDA, CFSAN)
- Form 483 Notice of Inspection – Warning Letter
- Summary of FDA/Company dialogue to ensure safe beverages with final action taken

# Key Points - Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices

- This guidance is intended for processors of refrigerated carrot juice and other refrigerated low-acid juices, which can pose a risk of botulism poisoning.
- Four cases of botulism linked to refrigerated carrot juice occurred in the United States and two cases occurred in Canada in September and October of 2006.." Because proteolytic *C. botulinum* spores are known to grow and produce toxin only under severe temperature abuse conditions, FDA is therefore modifying its earlier guidance on this issue
- Low-acid juices, such as carrot juice, that are distributed under refrigeration, and are not subject to the Low Acid Canned Foods regulation (21 CFR Part 113) may pose hazards associated with spore forming pathogens, specifically, toxins of non-proteolytic and proteolytic strains of *Clostridium botulinum*. Control measures for such juices are likely to involve multiple measures.
- FDA is now recommending that firms subject to the pathogen reduction provisions of the juice HACCP regulation incorporate validated control measures for all *C. botulinum* spores into their HACCP plans that will be applied in the processing facility and that will ensure that *C. botulinum* growth and toxin production will not occur should the juice, as offered for sale by the processor, be kept unrefrigerated above 50 deg F for an extended period

# What Happened?

- Audit overview
  - FDA Inspector as a messenger
  - CFSAN offsite main driver and investigative force
- Pertinent organism – Industry Standard verses FDA Carrot Juice Guidance
- Juice verses Nut Milk - Beverage
- Anaerobic versus aerobic environment
- HACCP Risk Assessment
- FDA dialogue – Science & Regulatory
- Form 483 and Response to Form 483
- Action mandated by FDA

# Key Learnings

- HPP is not equal to the perceived absolute kill of a thermal process
- FDA Enforcement by company directly related to size of consumer risk
- Lack of scientific evidence and Process Authority limits in understanding risk
- Increased industry data influences FDA enforcement guidelines
- Conclusions and implications for future FDA audit organization and overall structure

# Outcomes and Discussion Points

- Juice and Beverage Task Force formed
- Conclusions and implications for future FDA audit organization and overall structure
- Drugs dominate auditor training, food & beverage notably absent and apparent to Manufacturers being audited
- Separate Food and Drug divisions under combined FDA and USDA
- FDA could follow UK/European Model – Medicines Agency and a separate Food Standards Agency (UKFSA & EFSA)

# Supporting Information

- Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices
  - https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice updated November 10, 2017
- FDA Investigations and Operations Manual 2017
  - https://www.fda.gov/downloads/ICECI/Inspections/IOM/ucm127390.pdf
- UK Food Standards Agency
  - https://www.food.gov.uk
- European Food Standards Agency
  - https://www.efsa.europa.eu
- Food and Drink Federation – guidance to help manufacturers set the shelf-life of products
  - https://www.fdf.org.uk/product-shelf-life-guidance.aspx

# Summary

This experience taught us many things and encouraged us to change the relationship that manufacturing has within industry, academia and FDA Science & Regulatory.

- Create a truly collaborative environment
  - Task Force system to address collaboration
  - Encourage collaborative inspections
  - Create task force to improve inspection process
- Industry, Academia and Regulatory agreement on risks
  - *C. botulinum* guidelines & legislation
  - Pertinent organisms by food sector
- Food & Beverage audit training for all parties
- Science v Regulatory FDA Department involvement
- Separate Medicines and Food & Beverage Agencies

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Thank you

Questions?

# Abstract

Food Safety has become a household name. The acceleration of new products and processes has created a sense of urgency shared by the FDA and Industry. The food & beverage industry regulations and guidelines have previously been fairly straightforward to interpret their intent. However, there have recently been several cases in our careers that have challenged both the FDA and the entities we represented. We will provide a manufacturers perspective of one such case, leaving out the names of the companies and individuals involved. Suffice to say this example took 18 months to successfully resolve. It engaged the minds of microbiological and manufacturing experts in the US and UK. The business effect was minimized by engaging in dialogue with all parties and it has provided a process we now follow if such an event happens to a client with FDA involvement. Fact based discussions and decisions are essential. This case study illustrates that human interactions can successfully lead to a collaborative approach to food safety and quality, provided an open and brutally honest dialogue happens. Not all outcomes are successfully resolved, but we have used an approach that greatly increases the probability of a successful resolution and a safer food supply.