Making a Non-Thermal Validation Study Acceptable to a Regulator

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Outline

• Pathways to compliance
• Food additives: safety and regulatory status of emerging technologies
• FSMA: microbial hazards
Federal Regulations
Acts of Congress
Policies
Guidance Documents
COMPLIANCE
Food additives: safety and regulatory status of emerging technologies
FD&C Act

Adulteration under Section 402

Food shall be deemed adulterated if…

- Bears or contains an added poisonous or deleterious substance which may render it injurious to health [402(a)(1)]
- Bears or contains any food additive that is unsafe w/in the meaning of sec 409 [402(a)(2)(C)]
FD&C Act
Food Additives Amendment, 1997

• Defined the term food additive
• Exempted GRAS substances
Irradiation

• 21 CFR 179 – Irradiation in the production, processing and handling of food
  – Covers radiation sources, general provisions, ionizing radiation, radiofrequency (and microwave), ultraviolet, pulsed light and petitioned amendments.
Ultraviolet radiation for the processing and treatment of food may be safely used under the following conditions:

(a) The radiation sources consist of low pressure mercury lamps emitting 90 percent of the emission at a wavelength of 253.7 nanometers (2,537 Angstroms).

(b) The ultraviolet radiation is used or intended for use as follows:

- Food and food products: surface microorganism control
- Potable water: sterilization of water used in food production
- Juice/Juice Products: Reduction of human pathogens and other microorganisms

Other limitations apply
Examples

• To use higher UV intensities (i.e., > 1W per 5 to 10 ft$^2$) an interested party would have to petition the agency.

• The year 2000 final rule was specific for juice products and does not apply to any other foods.
Guidance for Industry

Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives

Additional copies are available from:
Office of Food Additive Safety, HFS-205
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 240-402-1200

http://www.fda.gov/FoodGuidances

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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Validation within FSMA

• Preventive controls need to be validated.

• Validation must include collecting and evaluating scientific and technical information (or … conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards.

21 CFR 117.160 (b)(1), (b)(2)
Approaches to Validation

- Government guidance
- Safe harbors
- Published scientific literature
- Mathematical models
- Data from microbial inactivation studies
GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES

CAC/GL 69 - 2008

Journal of Food Protection, Vol. 73, No. 1, 2010, Pages 140-202

Supplement

Parameters for Determining Inoculated Pack/Challenge Study Protocols

ADOPTED 20 MARCH 2009, WASHINGTON, D.C.
NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS

NACMCF Executive Secretariat, U.S. Department of Agriculture, Food Safety and Inspection Service, Office of Public Health Science, Room 333 Aerospace Center, 1400 Independence Avenue S.W., Washington, D.C. 20250-3700, USA

MS 09-287: Received 2 July 2009/Accepted 7 August 2009
Critical Factors

- radiation (e.g., UV)
- physical (e.g., time, distance from lamp)
- chemical (e.g., ozone concentration)
- thermal (e.g., temperature)
- mechanical (e.g., conveyor speed)
Pulsed Light Treatment of Black Peppercorns, 3 Hz

Population reduction

Surface Temperature

(Xu. 2016. MS Thesis IIT)
Plasma Treatment of Black Pepper

Salmonella Population [log (cfu/g)] vs. Time (s)

- Air-Argon Plasma
- Linear (Air-Argon Plasma)

Temperature (°C) vs. Time (s)

R² = 0.9839

Sun et al. 2014. *J. Food Sci.* 79(12)
Common Pitfalls of Validations

- Incomplete description of the process provided
- Critical factors and limits for the process not given.
- Impact of the food matrix not assessed
- Target pathogen inappropriate for product and process
- Suitability of the surrogate for each specific product and process.
Common Pitfalls of Validations

• Test methodology used for challenge study not provided
• Minimal data provided from biological test
• Replicate validation experiments to establish confidence in process delivery
• Statistical analysis inappropriate for data
• Critical factors and limits for the proposed process not given.
Often *Over-looked* Worst-Case Scenarios

- Min/Max values for the control measure
- Permitted manual operations
- Interactions between multiple control measures
- Loading and speed of conveying systems
- Capacity vs. load in a chamber/vessel
- Motion of conveying systems
- Hot and cold starts, ramp-up and ramp-down
- Equipment wear that can impact critical parameters
Thank you!