

# **FSPCA WEBINAR**

#### Updates to FDA's Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Spotlight on Appendix 1 February 22, 2024





Innovation Through Collaboration



# WELCOME AND INTRODUCTIONS

## **Kathy Gombas**

#### President, FSMA Solutions FSPCA Human Food Trainer of Trainers Work Group Co-Chair





# Agenda

DESCRIPTION	PRESENTER	TIME
Housekeeping	Kathy Gombas	1:00 – 1:05 CT
FSPCA News	Kathy Gombas	1:05 – 1:15 CT
Updates to FDA's Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Spotlight on Appendix 1	Lillian Hsu	1:15 – 2:15 CT
Q&A	All	2:15 – 2:30 CT





# Webinar Presentation and Recording

- Along with a PDF of the presentation, a portion of this webinar will be recorded and posted to the FSPCA website post-event.
  - The webinar recording is **view only**, download is not available
  - The Q&A portion of the webinar will **not** be recorded
- Please allow 5 business days for the presentation and recording to be published

#### FSPCA Events webpage: <u>https://www.fspca.net/events</u>





## Q&A

- All attendees are muted
- Ask questions by typing into the Chat box
  - Click on the Chat icon
    - To pose a question, begin by typing into the box that is provided on the screen and tap "Enter"
  - We will do our best to answer as many questions as time allows but we may not be able to address every question
  - Questions not relevant to this webinar topic, or questions that the presenters cannot provide a response to at this time will not be addressed

Attendees: Please do not answer questions posted in the Chat













# **FSPCA** Newsletter

- The FSPCA quarterly newsletter is a great way to receive the most current information related to FSPCA activities, such as educational and training opportunities, events, FSMA updates, and more.
- Join the FSPCA Listserv
- <u>Read our latest newsletter or view a past</u>
   <u>newsletter</u>
  - March newsletter coming soon!







# Upcoming FSPCA Webinars

 Animal Food Rule Inspectional Findings and Supplemental Resources for FSPCA Animal Food Lead Instructors



- Webinar registration is limited to <u>FSPCA Animal Food Lead Instructors only</u>
- **February 29** from 1:00 2:30 pm U.S. Central
- FSPCA Food Traceability Rule Awareness for Industry Module Webinar
  - Webinar registration is limited to <u>FSPCA Lead Instructors only</u>
  - April 9, 2024 from 1:00 2:30 pm U.S. Central (English)
  - April 11, 2024 from 1:00 2:30 pm U.S. Central (Spanish)

These webinars will be recorded. The presentation and a portion of the recording will be posted on appropriate Instructor Resource Portals post-event. **Note:** Q&A portion will not be recorded.





# SAVE THE DATE! FSPCA 2024 Annual Conference

- The 8<sup>th</sup> Annual FSPCA Conference will be held in person at the Chicago Marriott Southwest at Burr Ridge on November 19-20, 2024
- More information to come!
  - Agenda
  - Venue
  - Registration

Past FSPCA Annual Conference presentations are available on the FSPCA website







# UPDATES TO FDA'S DRAFT GUIDANCE FOR INDUSTRY: HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD: SPOTLIGHT ON APPENDIX 1

#### Lillian Hsu

Policy Analyst, Office of Food Policy and Response (OFPR) U.S. Food and Drug Administration (FDA)







# Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Spotlight on Appendix 1

FSPCA Lead Instructor Webinar February 22, 2024

> Lillian Hsu Policy analyst | OFPR OPPI











#### DESCRIBE THE REVISIONS MADE TO INTRODUCTION

DESCRIBE THE REVISIONS MADE TO APPENDIX 1: KNOWN OR REASONABLY FORESEEABLE ("POTENTIAL HAZARDS") DEMONSTRATE HOW REVISED APPENDIX 1 CAN BE USED AS A RESOURCE IN CONDUCTING THE HAZARD ANALYSIS

# Revised Introduction

- New title: Introduction and General Information Applicable to This Guidance
- Revised Introductory text to match changes to the way FDA describes part 117 since we first developed this Introduction, and to streamline it
- Definitions
  - Added ALL the terms defined in the regulation
  - Added definitions for terms that are for "the purpose of this guidance", including from later chapters
- Added section on training
- Added a new section on "Resources"
  - Includes titles and links to many FDA documents that are available on the internet (CPGs, Guidance for Industry, Import Alerts), Codex documents, resources specific to designing validation studies, and then a grab bag of "other resources"
- Added all the references used in all the chapters

# Revised Appendix 1

Revisions driven by stakeholder comments/concerns:

- Inconsistencies/concerns with certain hazard/commodity associations
  - Removed process-related hazards tables (formerly "Table 3" series)
    - Replaced with a discussion of the most relevant potential process-related hazards
  - Reorganization/revision of Food Groups, Categories, Subcategories, and certain hazards
    - Removed "Multi-component Foods" (Table K)
    - Added caveats (footnotes) for specific hazards marked as potential (with an "X")
  - Provided scientific, technical, or regulatory information to support certain potential hazard designations
- How FDA/State inspectors are using Appendix 1 during inspections
  - Added extensive introductory text to re-emphasize that
     Appendix 1 provides information on potential hazards (not a list of hazards requiring a PC)
- Other changes
  - Added sections on current food safety topics of interest (e.g. infant foods, chemical hazards)
  - Added discussion of "exceptional lethality"

IDA



# **Appendix 1 – Food Groups**



# Food Hazards and Controls Guide: Appendix 1

# Ingredient/Food-related Biological Hazards Tables

Table 1A: Known or reasonably foreseeable ("potential") food-related biological hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	Bacillus cereus	Clostridium botulinum	C. perfringens	<i>Brucella</i> spp.	Campylobacter spp.	Pathogenic <i>E. coli</i>	Salmonella spp.	L. monocytogenes	S. aureus	Parasites	Viruses	Comments
Bread, Biscuits, Rolls, Brownies, Cookies, Pizza, Pie Crust	1	- Unbaked Bakery Items - Ready-To-Bake (RTB) Dough - RTB Crust - With or Without Inclusions <sup>1</sup>	Refrigerated or Frozen						x	x	x				Includes bagels, croissants, puff pastry, phyllo

Tables 1A through 1P do not identify any hazards requiring a preventive control in any Food Subcategory. It is the responsibility of the owner, operator, or agent in charge of each food facility to determine, through hazard analysis, whether a biological hazard identified in Tables 1A through 1P as a known or reasonably foreseeable ("potential") biological hazard is a hazard requiring a preventive control in the facility's food product.



# Food Hazards and Controls Guide: Appendix 1 Ingredient/Food-related Chemical Hazards Tables

- Food Group 2A: Known or reasonably foreseeable ("potential") foodrelated chemical hazards for Bakery Items
- This Appendix does not include a Table of known or reasonably foreseeable ("potential") food-related chemical hazards for Bakery Items. Instead, for known or reasonably foreseeable ("potential") food-related chemical hazards for Bakery Items, you should see the Table(s) associated with the ingredients in your Bakery Item. For example:
- If your Bakery Item contains chocolate, you should consult Table 2D regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Chocolate and Candy.
- If your Bakery Item contains eggs, you should consult Table 2G regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Egg and Egg Products.
- If your Bakery Item contains wheat flour, you should consult Table 2J regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Grains, Pulses, Flours, and Starches.
- If your Bakery Item contains fruit, you should consult Table 2H regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Fruits and Vegetables.

## Food Hazards and Controls Guide: Appendix 1 Ingredient/Food-related Chemical Hazards Tables

Table 2J: Known or reasonably foreseeable ("potential") food-related chemical hazards for Grains, Pulses, Flours, and Starches

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Grains, Non-Rice	1	Whole and milled grains (e.g., flour and bran)	Ambient					<b>X</b> <sup>1</sup>	x	Wheat, Rye, Sorghum, Oats, Barley, Triticale, Buckwheat, Corn, Amaranth, Millet, Quinoa (RACs and milled grain products)
Rice, Milled Rice Products	2b	Rice (whole and milled) and rice products	Ambient		x	x		<b>X</b> <sup>2</sup>	x	White or Brown Rice, Rice protein, Sticky/sweet Rice, Basmati Rice, Jasmine Rice, Arborio rice, Rice-based noodles, Rice- based cereal

The Tables of Known or Reasonably Foreseeable ("Potential") Food-Related Chemical Hazards do not identify any hazards requiring a preventive control in any Food Subcategory. It is the responsibility of the owner, operator, or agent in charge of each food facility to determine, through hazard analysis, whether a chemical hazard identified in these Tables as a known or reasonably foreseeable ("potential") chemical hazard is a hazard requiring a preventive control for the facility's food product.

# **Potential Process-related Hazards**



Bacterial Pathogens – Presence/growth/toxin production due to survival of a lethal treatment	Undeclared food allergens – Incorrect label		
Bacterial Pathogens – Growth and/or toxin production due to poor time/temperature control	Unintended food allergen presence – Allergen cross-contact		
Bacterial Pathogens – Growth and/or toxin production due to poor formulation control	Chemical hazards due to mis- formulation (e.g., sulfites, yellow #5)		
Bacterial Pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP)	Process-contaminant hazards in certain plant-based foods		
Bacterial pathogens – Presence due to ingredients added after process controls	Metal		
Bacterial Pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity	Hard plastic		
Environmental Pathogens – Presence due to recontamination from the processing environment	Glass		

Food Hazards and Controls Guide, Appendix 1, section A1.7 Process and Facility Related Hazards

# Bacterial Pathogens – Presence/growth/toxin production due to survival of a lethal treatment

- Concern is vegetative pathogens surviving lethal treatment
- Lethal treatments include heat (most common), and nonthermal processes such as high-pressure processing (HPP), irradiation
- Typically, lethal treatment step will be a process preventive control that is validated
  - Validation can be in-house study or reference to reputable published information
- Exceptionally lethal heat treatments do not need to be identified as a process preventive control
  - Product undergoes severe heat process that vegetative pathogens cannot survive even in the absence of a preventive control or product would not be acceptable from a quality perspective if under-processed to the point where vegetative pathogens could survive

References Section 3.3.4.1 Section 4.3.1 Table 5-1 Chapter 6





# Bacterial Pathogens – Growth and/or toxin production due to poor time/temperature control

- Concern is pathogens growing in food that must be time/temperature controlled for safety (TCS)
- Controls:
  - Refrigerated storage of TCS food is likely a process preventive control
    - Includes RTE finished product food and work-in-process food that will not undergo Tak lethal treatment
    - Could include ingredients or work-in-process food that will be cooked if heatstable toxin could form due to time/temperature abuse before cooking
  - Measures to control time/temperature exposure during <u>unrefrigerated</u> processing of RTE food or work-in process food that could support pathogen growth and/or toxin formation likely are process preventive controls
  - Cooling hot food at time/temperature parameters to control pathogen growth/toxin formation likely is a process preventive control



References Section 3.3.4.2.1 Section 3.3.4.2.1 Section 4.3.2

Table 5-1



**Bacterial Pathogens – Growth and/or toxin** 

- Concern is pathogens growing in a shelfstable food that is supposed to be formulated to prevent such growth
- Formulation controls necessary to achieve shelf-stability likely would be process preventive controls including:
  - Water activity
  - рН
  - Water phase salt
  - preservatives

References
Section 3.3.4.2.3
Section 4.3.3
Section 4.3.4
Table 5-1





## **Bacterial Pathogens – Growth and/or toxin** production due to reduced oxygen packaging (ROP)

- Concern is Clostridium botulinum growing and forming toxin in food that is in reduced oxygen packaging (ROP)
- Refrigerated storage of food that can support C. *botulinum* growth and toxin formation likely a process preventive control
  - Includes finished product in ROP
  - Includes ingredients and work-in process food that are in ROP or in an anaerobic environment

#### References

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Section 3.3.4.2.4
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Table 5-1



Bacterial Pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity

- Concern is pathogens getting into packaged food due to loss of container's seal integrity
- Example:
  - RTE food pasteurized in a jar and then submerged in a cooling water tank
    - If pathogens are in the cooling water, they could be drawn into the hot jar via defective container closures or improper seals
- Measures such as checking containers, treating cooling water for pathogens are likely process preventive controls

References Section 3.3.4.4



# Environmental pathogens – Presence due to recontamination from the processing environment

- Concern is recontamination of RTE foods with environmental pathogens before packaging when product does not undergo subsequent lethal treatment and can support pathogen persistence/growth
- Environmental pathogens include *Salmonella* and *Listeria monocytogenes*
- RTE food includes finished products, and work-in-process foods or raw materials/ingredients that do not undergo a lethal treatment, such as:
  - Finished products: peanut butter
  - Work-in process foods or raw materials/ingredients: roasted ground peanuts added to peanut butter paste, fresh-cut produce in salad

References Section 3.3.5 Section 4.4 Table 5-2





# Environmental Pathogens – Presence due to recontamination from the processing environment (*cont'd*)

- Factors to consider in determining if the hazard is significant include:
  - Likelihood of environmental pathogens being in the facility
  - Potential routes of environmental pathogens to RTE food
    - Pathogens from plant environment to food-contact surfaces and RTE food
    - Pathogens getting into RTE food via employees
  - Likelihood of environmental pathogens being able to survive in the RTE food
- Sanitation preventive controls
  - Likely required at steps where RTE food is exposed to the environment
  - Includes cleanliness of RTE food-contact surfaces and employee practices
  - Environmental monitoring required as a verification activity

# Bacterial pathogens – Presence due to ingredients added after process controls

- Concern is *ready-to-eat* ingredients added to a product after a process control that could be contaminated with pathogens and there is no subsequent kill step after these ingredients are added
- Examples include:
  - Seasonings added to potato chips after the frying step

- Walnuts added as a topping to a cake after the baking step
- Preventive controls could include
  - Sanitation controls at facility where the RTE ingredients are exposed and handled during ingredient addition and product packaging steps
  - Supply-chain program to ensure that supplier(s) controlled pathogens that may be associated with the RTE ingredients

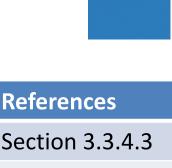


Table 5-1

## **Undeclared food allergens – Incorrect label**

- Concern is allergen that is intended to be in the food (i.e. part of the formulation) but is not declared on the label
- Currently, nine major food allergens
  - Food itself could be an allergen, or contain allergenic ingredients



# References Section 3.4.2 Section 3.4.2.1.2 Section 3.4.2.1.3

Section 3.4.2.2.3

Table 5-4

Chapter 11

# Undeclared food allergens – Incorrect label (cont'd)

- FDA
- Preventive controls to ensure proper labeling covers both:
  - Label content: accuracy of allergen declaration
    - Verify which allergens are supposed to be in the food
    - Develop label that correctly declares the allergens (label proofs)
    - Checking labels to make sure allergens are correctly listed either before accepting the labels for use or at the labeling/packaging step
  - Label application: correct label for the intended product
    - E.g. peanut butter cookies are packaged in containers labeled as peanut butter cookies

## Unintended allergen presence – allergen cross-contact

- Concern is allergen(s) present in a food that is not supposed to have the allergen(s) in it
  - Foods that contain different allergens
  - Foods with and foods without allergens

ReferencesSection 3.4.2Section 3.4.2.1.4Table 5-4Chapter 11

Allergen cross-contact may be due to:	Controls
Using shared equipment	<ul> <li>Cleaning between products with unlike allergens or between allergen-containing and non- allergen-containing products</li> <li>Thoughtful production scheduling</li> </ul>
Airborne transfer of allergens in processing areas	<ul> <li>Performing production activities in ways that minimize likelihood of airborne transfer</li> </ul>
Employee handling	<ul> <li>Ensuring proper employee handwashing, changing of gloves, garments, etc</li> </ul>
Storage in exposed packaging/containers	<ul> <li>Separating and identifying allergens in storage and keeping packages closed</li> </ul>
Addition of the wrong ingredient that introduces an allergen	<ul> <li>Ensuring the right ingredients are used</li> </ul>

# Allergen cross-contact: role of voluntary allergen advisory statements



- Allergen advisory statements
  - Voluntary
  - E.g. "may contain [allergen]"
  - May be appropriate if facility cannot provide adequate assurance that food has been protected from allergen cross-contact, even with appropriate CGMPs and allergen cross-contact preventive controls in place
    - Does not remove obligation to adhere to CGMP and preventive controls requirements, as applicable
  - Must be truthful and not misleading
  - Strategically designed/placed so noticeable by the allergic consumer
- If the PCQI determines allergen advisory statements are appropriate:
  - PCQI should provide written justification in the food safety plan as to why existing control measures cannot ensure the food is protected from allergen cross-contact

# Chemical hazards due to mis-formulation (e.g., sulfites, yellow #5)

Concern is presence of a food or color additive

associated with a food intolerance in a food that

either is not formulated to contain that additive,

or presence at levels beyond the maximum use

level for safety



#### References

Section 3.4.2.2

Section 3.4.2.2.2

FDA Website: <u>Substances</u> added to Food

Examples	Controls
Mis-formulation resulting in Yellow #5 being in a product that is not supposed to have it	<ul> <li>Ensure yellow #5 is not mistakenly added</li> </ul>
Mis-formulation resulting in sulfiting agents present when not supposed to be in the product	<ul> <li>Ensure that sulfites are not mistakenly added</li> </ul>
Mis-formulation resulting in an additive or GRAS substance present in excess of maximum use levels for the food	<ul> <li>Ensure that excessive amounts of the additive are not used</li> </ul>

# Process-contaminant hazards in certain plant-based food (produced during heating)

FDA

- Concern is formation of chemical contaminants during high heating of certain products that could pose a health concern
- Examples:
  - Acrylamide in starchy products such as potato chips
  - 3-monochloropropane-1,2-diol esters (3-MCPDEs) and glycidyl esters (GEs) in refined oils
- Recommend reviewing the following resources, as appropriate:
  - <u>Guidance for Industry: Acrylamide in Foods</u>
  - FDA website: 3-Monochloropropane-1,2-diol (MCPD)
     Esters and Glycidyl Esters

#### References

Section 3.4.2.3

<u>Guidance for Industry:</u> <u>Acrylamide in Foods</u>

FDA website: 3-Monochloropropane-1,2-diol (MCPD) Esters and Glycidyl Esters

# Metal

- Concern is metal inclusion in food
- Sources can include:
  - Metal machinery
  - Metal parts in equipment
  - Raw materials
- Controls can include:
  - Metal detectors
  - Magnets and screens/sieves
  - Visual inspection of equipment for damaged or missing parts
  - X-ray detection system



# ReferencesSection 3.5Table 3-9Section 4.3.8.1FDA Compliance Policy<br/>Guide (CPG) 555.425

# Glass

- Concern is glass fragments in food when product is packed/packaged in glass containers
- Handling/packing/packaging methods for glass containers can result in broken/chipped glass getting into the food
- Controls include:
  - Visual inspection of containers for damage
  - Visual inspection of packaging line for broken glass
  - X-ray detection system

ReferencesSection 3.5Table 3-9Section 4.3.8.2

# Hard plastic

- Concern is hard plastic inclusion in food which can be a health hazard
- Sources of hard plastic can include:
  - Equipment
  - Utensils
  - containers
- Controls include:
  - Visual inspection of containers, equipment, utensils for damage or missing pieces
  - X-ray detection system



References Section 3.5 Table 3-9 FDA Compliance Policy Guide (CPG) 555.425

# Finished Product: Potential Hazards



- For the finished product, do not use Tables 1 & 2 in Appendix 1
  - Those hazards will be addressed in the ingredient hazard analysis
- Use section A1.7 Process and Facility Related Hazards in Appendix 1
  - Process-related hazards for the finished product
    - Biological, chemical, or physical hazards related to the processing of the finished product at the facility

# Finished Product: Potential Process-related Hazards



Bacterial Pathogens – Presence/growth/toxin production due to survival of a lethal treatment	Undeclared food allergens – Incorrect label
Bacterial Pathogens – Growth and/or toxin production due to poor time/temperature control	Unintended food allergen presence – Allergen cross-contact
Bacterial Pathogens – Growth and/or toxin production due to poor formulation control	Chemical hazards due to mis- formulation (e.g., sulfites, yellow #5)
Bacterial Pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP)	Process-contaminant hazards in certain plant-based foods
Bacterial pathogens – Presence due to ingredients added after process controls	Metal
Bacterial Pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity	Hard plastic
Environmental Pathogens – Presence due to recontamination from the processing environment	Glass

Section A1.7 Process and Facility Related Hazards in Appendix 1

# Ingredients: Potential Hazards



- Use Appendix 1 to identify <u>potential hazards</u> for the ingredients
  - Use Tables 1 and 2 to identify ingredient-related biological and chemical hazards
  - Use section A1.7 to identify process-related hazards
    - We have streamlined them for simplicity and efficiency

# Ingredients: Streamlined Section A1.7 Process and Facility Related Hazards



Do process-related pathogen hazards\* (e.g., presence, survival, growth, toxin formation, recontamination) at the supplier require a PC for this ingredient?

Do <u>undeclared allergens</u> (intentional allergens not declared on label) at the supplier require a PC for this ingredient?

Does <u>allergen cross-contact</u> (from unintentional

incorporation of allergens) at the supplier

require a PC for this ingredient?

Do chemical hazards due to mis-formulation

(e.g., addition of food/color additives such as

sulfites or yellow #5) at the supplier require a

PC for this ingredient?

Do metal or hard plastic at the supplier require

a PC for this ingredient?

Does <u>glass</u> at the supplier require a PC for this ingredient?

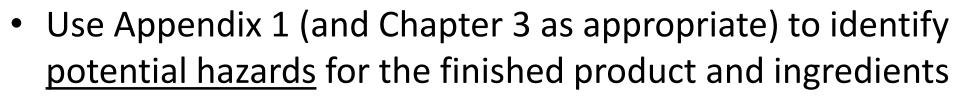
(only applicable if ingredient packed in glass containers)

- Bacterial Pathogens Presence / growth / toxin production due to survival of a lethal treatment
- Bacterial Pathogens Growth and/or toxin production due to poor time/temperature control.
- Bacterial Pathogens Growth and/or toxin production due to poor formulation control.
- Bacterial Pathogens Growth and/or toxin production due to reduced oxygen packaging (ROP)
- Bacterial pathogens Presence due to ingredients added after process controls.
- Bacterial Pathogens Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity
- Environmental Pathogens Presence due to recontamination from the processing environment.

\*Also includes pathogen cross-contamination (from Fresh-cut Produce guidance)

Essentially, 8 process-related pathogen hazards are consolidated and considered together (i.e., pathogens in ingredients at the supplier level)

# Summary: Identifying potential hazards using Appendix 1



Hazard Analysis	Tables 1 & 2	Section A1.7 Process and Facility Related Hazards
Finished Product		x
Ingredient	х	x

 Then, evaluate the potential hazards to determine whether each of them requires a preventive control

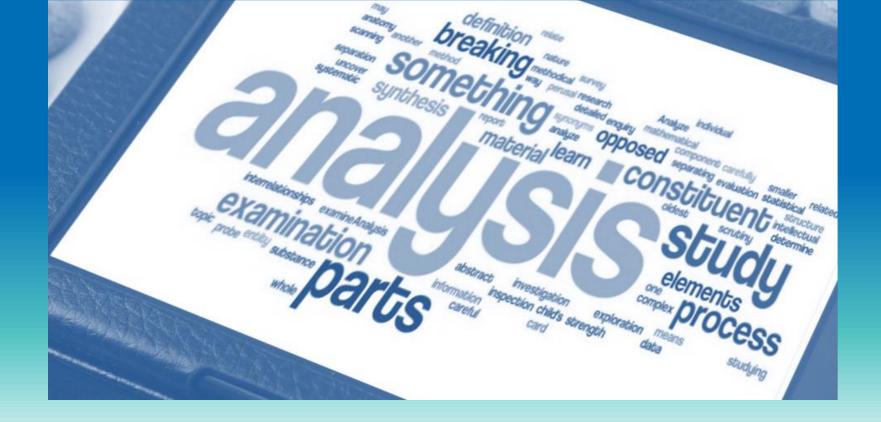
# Questions?

If you have any questions, please contact the FSPCA at **fspca@iit.edu** or or visit the FSPCA website at <u>https://www.fspca.net/</u> for resources on preventive controls, lead

instructor applications, and details of other FSPCA activities.







# THANK YOU!





Innovation Through Collaboration