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Preface	PPT Slide 7	FSPCA Website: https://www.ifsh.iit.edu/fspca
2	2-3	FDA Outbreak Data: https://www.fda.gov/food/outbreaks-foodborne- illness/investigations-foodborne-illness-outbreaks
2	2-3	FDA Reportable Food Registry Reportable Food Registry: https://www.fda.gov/food/compliance-enforcement-food/reportable- food-registry-industry
		FDA's RFR Data Dashboard: <u>https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard?utm_medium=email&utm_source=govdelivery</u>
3	3-15 (bottom slide)	FDA Guidance Human Food By-Products for Use as Animal Food: <u>https://www.fda.gov/files/animal%20&%20veterinary/published/CVM-GFI-</u> <u>-239-Human-Food-By-Products-For-Use-As-Animal-Food.pdf</u>
3	3-16	FDA Defect Action Levels Handbook: https://www.fda.gov/food/ingredients-additives-gras-packaging- guidance-documents-regulatory-information/food-defect-levels- handbook
4	4-3 (top slide)	FDA's RFR Data Dashboard: https://www.fda.gov/about-fda/fda-track- agency-wide-program-performance/fda-track-reportable-food-registry- data-dashboard?utm_medium=email&utm_source=govdelivery
5	5-3 (bottom slide) and 5-4 keynote box	FDA's Guidance on Action Levels for Poisonous or Deleterious Substances in Human and Animal Feed: https://www.fda.gov/regulatory- information/search-fda-guidance-documents/guidance-industry-action- levels-poisonous-or-deleterious-substances-human-food-and-animal-feed
5	5-5 (top slide)	FDA's RFR Data Dashboard: https://www.fda.gov/about-fda/fda-track- agency-wide-program-performance/fda-track-reportable-food-registry- data-dashboard?utm_medium=email&utm_source=govdelivery
5	5-7	Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5): https://www.fda.gov/regulatory-information/search- fda-guidance-documents/guidance-industry-questions-and-answers- regarding-food-allergen-labeling-edition-5



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5	5-7	Food Intolerances - Sulfites: Sulfites are considered a "food hypersensitivity" which refers to an abnormal physiological response to a particular food. Food hypersensitivities can be divided into two major categories: food allergies and food intolerances. Food Intolerances are adverse reactions to foods that are non-immunological, for example, Idiosyncratic reactions, e.g., induced asthma from ingesting sulfites. Sulfites added to foods must be declared. The only exception is made when sulfites are added indirectly (i.e., through a sulfited ingredient such as sulfited apple chunks in apple/cinnamon cream cheese) and the sulfite level in the food product (such as the cream cheese) is below 10 ppm. In such cases, sulfite label declaration is required if the sulfite content, determined as SO2 by a prescribed analytical method, is 10 ppm or higher.
5	5-8 (top slide)	FDA's Recall Data Dashboard: https://datadashboard.fda.gov/ora/cd/recalls.htm
5	5-9 - first instructor note re: exemption petitions	FDA Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications: https://www.fda.gov/regulatory-information/search- fda-guidance-documents/guidance-industry-food-allergen-labeling- exemption-petitions-and-notifications Inventory of Petitions Received under 21 U.S.C. 343(w)(6) for Exemptions from Food Allergen Labeling: <a href="https://www.fda.gov/food/food-labeling-
nutrition/inventory-petitions-received-under-21-usc-343w6-exemptions-food-allergen-labeling">https://www.fda.gov/food/food-labeling- nutrition/inventory-petitions-received-under-21-usc-343w6-exemptions- food-allergen-labeling
5	5-13	FDA Pesticide Residue Monitoring Program Reports and Data on FDA's website: The webpage has annual reports that have been prepared to summarize results of the U. S. Food and Drug Administration's (FDA) pesticide residue monitoring program for food products https://www.fda.gov/food/pesticides/pesticide-residue-monitoring- program-reports-and-data
5	5-18 (bottom slide) and 5-17 keynote box	FDA Compliance Policy Guide 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects: <u>https://www.fda.gov/regulatory-</u> information/search-fda-guidance-documents/cpg-sec-555425-foods- adulteration-involving-hard-or-sharp-foreign-objects
5	5-21	Congressional Research Service Report Food Fraud and "Economically Motivated Adulteration" of Food and Food Ingredients: https://crsreports.congress.gov/product/pdf/R/R43358/4
7	7-5	FDA FSMA Website: https://www.fda.gov/food/guidance-regulation- food-and-dietary-supplements/food-safety-modernization-act-fsma
7	7-6	FDA Technical Assistance Network: <u>https://www.fda.gov/food/food-</u> safety-modernization-act-fsma/fsma-technical-assistance-network-tan
FDA Draft Guidance Slides	Slide 1	FDA Draft Hazard Guide (Chapters & Appendices): https://www.fda.gov/regulatory-information/search-fda-guidance- documents/draft-guidance-industry-hazard-analysis-and-risk-based- preventive-controls-human-food



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FDA Draft Guidance Slides	Slide 13	FDA Appendix 1: https://www.fda.gov/media/99581/download
FDA Draft Guidance Slides	Slide 14	Food Control Methods Look up Appendix 1: https://www.foodcontrolmethods.com/potentialhazards/hazardlookup
10	10-3	You must identify the specific species for tree nuts, fish and crustacean shellfish. Where do you find species names:
		Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5): https://www.fda.gov/regulatory- information/search-fda-guidance-documents/guidance-industry- questions-and-answers-regarding-food-allergen-labeling-edition-5 FDA Seafood List to identify acceptable market names for allergen labeling for fish and crustacean shellfish: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=SeafoodList
10	10-18 (bottom slide) – keynote box	FARRP Food Labelling for the Food Allergic Consumer - See Precautionary Labeling Examples: <u>https://farrp.unl.edu/food-labelling-food-allergic-</u> <u>consumer</u>
10	10-25 2 nd reference	FARRP Components of an Effective Allergen Control Plan: Framework for Food Processors: https://farrp.unl.edu/allergen-control-food-industry
11	11-15	FDA Draft Guidance for Industry Control of Listeria: Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods FDA
12	12-6	FDA Supply Chain Disclosures: <u>https://www.fda.gov/regulatory-</u> information/search-fda-guidance-documents/draft-guidance-industry- describing-hazard-needs-control-documents-accompanying-food- required-four
12	12-6	FDA Supply Chain Customer Written Assurances: FDA Guidance for Industry: PC, FSVP, IA, and Produce Safety regulations: Enforcement Policy Regarding Certain Provisions: <u>https://www.fda.gov/regulatory-</u> information/search-fda-guidance-documents/guidance-industry- current-good-manufacturing-practice-and-preventive-controls-foreign- supplier
12	12-11	Evaluating Supplier Regulatory Compliance Performance: FDA Compliance Data Dashboard: https://datadashboard.fda.gov/ora/index.htm
12	12-14 (top slide)	FDA Temporary Policy Regarding PC Supplier Verification onsite Audit Requirements during COVID: <u>https://www.fda.gov/regulatory-</u> information/search-fda-guidance-documents/temporary-policy- regarding-preventive-controls-and-fsvp-food-supplier-verification-onsite- audit



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12	As needed	FDA Firm/Supplier Evaluation Resources: FDA Draft Hazard Guide Chapter 15: Supply-Chain Program for Human Food Products: https://www.fda.gov/media/110443/download
15	As needed	FSPCA Recall Plan Template https://www.ifsh.iit.edu/fspca/fspca-materials Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry – Chapter 14: Recall Plan https://www.fda.gov/media/131287/download Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff: https://www.fda.gov/regulatory- information/search-fda-guidance-documents/initiation-voluntary-recalls- under-21-cfr-part-7-subpart-c Product Recalls, Including Removals and Corrections Guidance for Industry: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections FDA's Recall Data Dashboard: https://datadashboard.fda.gov/ora/cd/recalls.htm
15	15-6	FDA Recall Coordinators: <u>https://www.fda.gov/safety/industry-</u> guidance-recalls/ora-recall-coordinators

ADDITIONAL RESOURCES

- FSMA Rules and Guidance: <u>https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry#guidance</u>
- FDA Regulation Pocket Books: <u>https://www.gmppublications.com/ProduceGMPs.html</u>
- FDA PCHF Small Entity Compliance Guide: <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-what-you-need-know-about-current-good-manufacturing-practice-hazard</u>
- FDA Guidance for Industry: Determination of Status as a Qualified Facility: <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility</u>
- FDA PCHF Inspection Compliance Program 7303.040: https://www.fda.gov/media/131744/download
- FDA Compliance Data Dashboard Inspections (including top 10 citations), Compliance Actions, Recalls, Imports Summary, Import Refusals, Import Entries: <u>https://datadashboard.fda.gov/ora/index.htm</u>
- WHO REGULATES EGGS (FDA vs USDA) <u>https://www.registrarcorp.com/resources/fda-usda-food-regulations/</u>



FSPCA LEAD INSTRUCTOR RESOURCES

- PCHF Participant Course Advertising Requirements (Form 0028): https://www.ifsh.iit.edu/sites/ifsh/files/departments/fspca/pdfs/FSPCA_FORM_0028_Advertising-Requirements HF 20220812.pdf
- Instructor Resource Portal (IFPTI): https://ifpti.absorbtraining.com/#/login
- FSPCA Community: <u>https://fspca.force.com/FSPCA/s/?language=en_US</u>