Foreign Supplier Verification Programs (FSVP)
Errata Sheet from Version 1.0 to 1.1 – Participants

Below you will find changes made to the FSPCA Foreign Supplier Verification Programs course: Version 1.0. Those with Version 1.0 will need to address all changes within their material.

Abbreviations for materials: *PPTs=PowerPoints, PM = Participant Manual, EW=Exercise Workbook, KP=Key Point, RN=Resource Note, PP=Paragraph*

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GLOBAL CHANGES						
PM, EW	Front (inside) Cover					Added the full version "Copyright Notice" on the inside of front cover that says: **Copyright Notice** The Foreign Supplier Verification Programs (FSVP) training curriculum was developed by the Food Safety Preventive Controls Alliance (FSPCA). The FSPCA is a broad-based public-private alliance of key industry, academia and government stakeholders. It was established in late 2011 by a grant from the U.S. Food and Drug Administration (FDA) to Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH). © 2017 Illinois Institute of Technology (IIT) Institute for Food Safety and Health (IFSH). All rights reserved.
PM, EW	All	All	All	All		Added the short version "© 2017 IIT IFSH" to the footer on all inside pages.
PPT, PM, EW	All	All	All	All	All	Unbolded "qualified individual" Changed any reference to "FSVP qualified individual" to "your qualified individual under the FSVP rule" or "your qualified individual" (unless the language is directly from the rule)
PPT, PM, EW	All	All	All	All	All	Ensured any reference to the full regulation "Current Good Manufacturing Practice, Hazard Analysis, and Risk-based

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						Preventive Controls for Food for Animals" regulation is worded as "food for animals," not "animal food." When NOT using the full name of the rule, use "…for animal food."
PPT, PM, EW	All	All	All	All	All	Ensured any reference to the "Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food" regulation is worded as "human food," not just "human."
PPT, PM, EW	All	All	All	All	All	Changed U.S. Customs and Border Protection (CBP) entry forms and/or entry paperwork to CBP entry filing or entry process where applicable.
PPT, PM, EW	All	All	All	All	All	Changed "known and reasonably foreseeable hazards" to "known or reasonably foreseeable hazards" (ensured that "reasonably" is included in text)
PPT, PM, EW	All	All	All	All	All	Added the word "significantly" in front of "minimize" when referring to hazards, e.g., "significantly minimize and control hazards" or "significantly minimize and prevent hazards"
PM	All	All	All	All		Removed any statement re: FDA has not published guidance on FSVP, as they have.
PPT, PM, EW	All	All	All	All	All	Removed the "s" from "CGMPs" (especially when referring to rule directly)
PPT, PM, EW	All	All	All	All	All	Verified that any text referring to "written assurances" in relation to extensions to date of compliance applies to U.S. suppliers downstream only. They do NOT apply to foreign suppliers.
PPT, PM, EW	All	All	All	All	All	Ensured that all wording referring to "standard" is "food safety standard." (Note: Performed a word search for "safety" to verify use of food when appropriate.) Mirrored this wording when applicable: "As noted earlier, the FSVP rule is about ensuring that imported foods meet the

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						same level of food safety standards that are required of food produced in the U.S."
						Ensured that instructor notes and key points are uniform: • Used hand symbol for any engagement opportunity ✋ used the word "Engagement" only and specified what the engagement is (discussion, group activity, etc.) Deleted the words "Instructor's Note" when using this symbol. • Used the book icon to indicate resources 🕮 and used the word "Resources" after the icon. • Used the key icon for key points 🗝 and used the words "Key Point" after it—NOTE: Not every white text box is a Key Point; some are definitions or resources.
PPT, PM	Multiple					Deleted the "Questions" slide where there is an exercise at the end of the chapter.
PPT, PM	Multiple					Added a slide for the exercise instructions, if there is an exercise at the end of the chapter; added a slide for each exercise, if there is more than one.
ACKNOWLEDGEMENTS & TABLE OF CONTENTS CHANGES						
PM		v				Changed "Chapter 3: Overview of Requirements" to "Chapter 3: Overview of the Requirements" Changed "PCPS Session: Preventive Controls and Produce Safety Session" to "PCPS: Preventive Controls and Produce Safety Session" Changed "Chapter 7: Reevaluation of Foreign Supplier" to "Chapter 7: Reevaluation of Foreign Supplier Performance and Food Risk, and Corrective Actions"

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						Changed "Chapter 8: Importer Identification" to "Chapter 8: Importer Identification at Entry" Changed "Appendix 1: FSVP Summary and Rule" to "Appendix 1: FSVP Summary, Rule, and Guidance"
PREFACE CHANGES						
PM	Preface	P-1				Added a new textbox on the right-hand side of the page, describing the Key Point and Resources icons that are used throughout the PM.
PPT	Preface	Slide 3	PPT Only		1	Added new slide 3 "Housekeeping"
PPT, PM	Preface	Slide 4			1	Moved previous slide 3 "Introductions" and related text on page P-2. Added two new bullets (Bullets 3 and 4): "Products you import" and "What you hope to get out of the course"
PPT, PM	Preface	Slide 5 P-3	All	All	1	Added new slide 5 "Food Safety Preventive Controls Alliance (FSPCA)" Added new text beneath slide that says: The FSPCA was established in 2011 as part of a grant from FDA to the Illinois Institute of Technology's Institute of Food Safety and Health. The purpose of this broad-based alliance is to develop and maintain a cost-effective education and training program to assist the food industry with understanding and achieving compliance with certain aspects of FSMA. FSPCA's mission is to support safe food production by developing a standardized curriculum and technical educational materials on FSMA regulations and providing technical assistance outreach to the food industry.
PPT, PM	Preface	Slide 6 P-4			1	Moved previous slide 4 "Disclosure" and related text previously on page P-3 to page P-4.

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PPT, PM	Preface	Slide 7 P-5	PP 1 PP 2	1 1 & 2	1	Moved previous slide 5 “Food Safety Preventive Controls Alliance” and related text previously on pages P-3 & P-4 to page P-5. Changed title to “FSPCA FSVP Curriculum” and reworded the first bullet to say: This curriculum was designed by regulatory, academic, and industry professionals and developed with funding from FDA as part of the FSPCA. Reworded the first paragraph of the text beneath slide to say: This curriculum was designed by regulatory, academic, and industry professionals and developed with funding from FDA as part of the FSPCA. While FDA assisted in the preparation of the course materials, the materials have been written and produced by the Alliance and are not official FDA materials. Deleted the opening phrase of the second paragraph, “In contrast to the Preventive Controls (PC) rules” Added “a” between “following” and “standardized curriculum”
PPT, PM	Preface	Slide 8 P-6	1 2	1 & 2 4		Moved previous slide 6 “Course Description and Target Audience” and related text previously on page P-4 to page P-6. Changed the first sentence in the paragraph beneath slide to say: This course will provide participants with a thorough understanding of the requirements of the “Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals” regulation of the U.S. Food and Drug Administration (FDA).

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						Changed the text in paragraph 1, line 3, which previously said "…if no owner of Consignee…"; corrected it to say "…if no owner or Consignee…"
PPT, PM	Preface	Slide 9			1	Moved previous slide 8 "Course Goal and Objectives" and related text previously on page P-5 to page P-7. Changed "Goal" to say: Participants should be able to determine how to comply with FSVP requirements." Changed Objective #2 to "Explain how to develop an FSVP." Changed Objective #3 to "Describe how to implement an FSVP." Changed Objective #4 to "Describe how to implement an FSVP recordkeeping system." Changed text beneath slide to align with slide.
PM	Preface	Slide 10 P-7 & P-8				Moved previous slide 8 "What Will the FSVP Course Not Do?" and related text previously on pages P-5 & P-6 to page P-7 & P-8. Reworded sub-bullets on slide to say: • Preventive Controls (FSPCA courses, PC for Human Food and PC for Animal food, are available) • Produce Safety (Produce Safety Alliance course is available) • All FDA food safety regulations, all labeling, and other requirements for foods • Answering all questions about how FSVP applies to individual import arrangements • FDA facility registration, prior notice

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PPT, PM	Preface	Slide 11 P-8	All	All	1	Added new slide 11 “Course Materials” Added new text beneath slide that says: The FSVP training materials includes an agenda (located at the end of the Preface), a participant manual, and an exercise workbook. The manual and exercise workbook are yours. Become familiar with them and use them as a reference. The manual contains references and forms that can help you develop an FSVP and resources to locate other basic information. Make as many notes and marks in the manual as needed to assist you in creating an understanding of FSVP. This manual does not have a copyright. Make as many copies of the forms as necessary or copy the whole manual to share with others in your company.
PPT, PM	Preface	Slide 12 P-9	PP 2-5		1	Moved previous slide 9 “Course Format” and related text previously on page P-6 to page P-9. Added additional paragraphs that say: Chapters 1, 2, and 3 will help to explain WHY and HOW the FSVP rule came about; WHO it applies to, i.e., who is an FSVP “importer;” WHAT are the requirements, i.e., standard and modified, and HOW they apply to a particular situation. Chapters 4 through 9, focus on explaining the core elements of an FSVP, i.e., hazard analysis, evaluation and approval of foreign supplier, verification and corrective actions, reevaluation, importer identification at entry, and records and documentation. The final chapter, Chapter 10, focuses on FDA oversight of FSVP importers and their implementation of the FSVP requirements.

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						There are ten appendices located at the end of this manual. They are included as a resource to provide you with more information and to help you develop your FSVP. We will review the appendices in more detail in the next slide.
PPT, PM	Preface					Deleted "Chapter Preview slides, previous slides 10-20 and related text previously on pages P-7-P-13.
PPT, PM	Preface	Slide 13 P-10			1	Added new slide 13: "Preview of Appendices" Added new text beneath slide that says: As you learn more about developing an FSVP, there are many definitions that you need to understand. Refer to Appendix 10 as needed. You may also want to add other terms that you may need in developing and implementing your own FSVP.
PPT, PM	Preface	Slides 14-16 P-10 – P-11				Moved previous slides 21-23 and related text previously on pages P-13 – P15 to pages P-10 – P-11.
PPT	Preface	Slides 17-18	PPT Only			Added new slides 17-18, "Course Agenda—Day One" and "Course Agenda—Day Two" respectively (PPT only).
PM	Preface	P-12				Added new paragraph that says: The participant course agenda is intended to be covered as a 2-day (16 hours) course, which includes frequent opportunities for review and classroom exercises designed to provide learning opportunities to thoroughly understand the FSVP rule. The time allotted to each section will vary based on the audience and level of familiarity with the FSVP rule. A typical agenda appears on the next page.
PM	Preface	P-13				Added the "Agenda."
CHAPTER 1 CHANGES						
PM	Ch. 1	1-2	KP			Moved KP previously on page 1-1 to page 1-2.

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						Added second sentence to the KP that says: And, you, as a U.S. importer of food, have the responsibility of ensuring that your foreign suppliers are doing what they need to do in order to meet those requirements.
PPT, PM	Ch. 1	Slide 6			1	Changed first bullet on slide to say: Issuing regulations and guidance that establish food safety standards that help ensure food is safe to eat.
PM	Ch. 1	Slide 8			1	Added citation for the CDC data: [1]Scallan, E., Griffin, P. M., Angulo, F. J., Tauxe, R. V., & Hoekstra, R. M. (2011). Foodborne Illness Acquired in the United States—Unspecified Agents. *Emerging Infectious Diseases, 17*(1), 16-22. https://dx.doi.org/10.3201/eid1701.P21101
PPT, PM	Ch. 1	Slide 12 1-8 and 1-9	PP 1 on 1-9		2 on 1-8	Added new slide 12 “FDA Examples of Problems with Imported Food.” Added new text beneath slide that says: On the slide above, we have some examples of problems (in the past and currently) that FDA identified with imported food. Actions taken by FDA included import alerts and recall in some instances.
PPT	Ch. 1	Slide 13			1	Combined and edited previous slides 12 and 13 to say: • FSMA amended the FD&C Act to put more emphasis on preventing food hazards by requiring that: o Hazards be systematically identified, and o Controls be systematically implemented to prevent those hazards. • FSMA addresses the safety of human and animal food (including fresh produce and processed food) throughout the supply chain.

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						• FSMA provides FDA with new tools to ensure that food for U.S. consumers is safe whether it is produced in the U.S. or elsewhere
PM	Ch. 1	1-9	PP 1 PP 4	5 All		Added the words "significantly minimize or" to second sentence in first paragraph to say: For example, the approach under the PC rules is to require that hazards needing control be systematically identified by producers, and then to require that controls be systematically implemented to significantly minimize or prevent those hazards from occurring. Deleted first sentence previously on page 1-10 that said: The objective of FSMA is to ensure that U.S. consumers are not exposed to avoidable food hazards, no matter where the foods are produced. Added text previously on page 1-10 to page 1-9 as last paragraph to say: In passing FSMA, Congress recognized that new tools were needed to ensure food safety and that FDA needed access to additional information and enforcement authorities.
PM	Ch. 1	1-10	KP			Added KP that says: FDA proposes rules, so it can receive comments from anyone affected by the rule and others, whether they be food importers, trade groups, brokers, the general public, foreign governments, or anyone else. In the case of the FSVP rule, FDA also published a supplemental proposal in response to comments received on the initial proposal, giving a second opportunity for public comments on portions of the proposed FSVP rule.
PPT, PM	Ch. 1	Slide 15			2	Changed slide to say: • FDA publishes a proposed rule that invites public comments

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						• FDA responds to the issues raised by the public comments in the preamble to the final rule • The final rule is then published in the Federal Register
PM	Ch. 1	1-11	RN			Added a Resource Note that replaced previous Resource Note and Key Point to say: **Information on the PC rules and the Produce Safety rule:** **Brief Overview:** A brief overview of the PC rules and the Produce Safety rule will be discussed later in the course in the PCPS Session. **Additional Information:** For additional information on the Preventive Controls (PC) rules for human and animal food, refer to Appendix 6a of this manual. For additional information on the Produce Safety rule, refer to Appendix 6b of this manual. **Courses on PC and Produce Safety rules:** Separate, multi-day standardized courses on the PC rules and the Produce Safety rule are being offered for those who want a more detailed understanding of those rules. Information and links are available in Appendix 7 of this manual.
PPT	Ch. 1	Slide 16			1	Combined and edited previous slides 16-18 into one slide that says: • 21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (also known as the CGMP and PC rule for human food or just PC rule for human food); published September 17, 2015 • 21 CFR Part 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (also known as the CGMP and PC rule for animal food or PC rule for animal food); published November 27, 2015

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						• 21 CFR Part 112 – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (also known as the Produce Safety rule [PS]); published November 27, 2015
PM	Ch. 1	1-11 to top of 1-12	PP 1 & 2	All		Combined and edited text beneath previous slides 16-18 previously on pages 1-12 and 1-13 to say: Whether you import food for humans or animals, either raw or processed food, your foreign suppliers likely will need to adhere to one of these regulations described in this or the next two slides. The Preventive Controls (PC) rules, of which there are two, one applying to human food (Part 117) and the other to animal food (Part 507), require that facilities that manufacture, process, pack or hold food must implement preventive risk-based controls to ensure food safety. The PC rules for human and animal food apply to both foreign and domestic manufacturers/processors and others. The Produce Safety rule (Part 112) sets requirements for good agricultural practices that apply to foreign and domestic growers of produce, and others.
PM	Ch. 1	1-12	RN			Added RN that says: A copy of the Federal Register FSVP rule without the preamble can be found in Appendix 1 of this manual.
PM	Ch. 1	1-12	RN			Added RN regarding FDA guidance that says: While FDA has not published their main guidance document, it is worth mentioning that FDA has published three FSVP related guidance documents as of this printing. • Guidance for Industry: Recognition of Acceptable Unique Facility (UFI) for the Foreign Supplier Verification Programs Regulation https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm

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						• Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the FSVP Regulation https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm • Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm524553.htm
PM	Ch. 1	1-12	PP 3	3-10		Bolded and revised paragraph beneath slide to say: The preamble is especially useful because it explains why FDA made the decisions it made in writing the proposals and the final rule. It also provides guidance for importers in explaining how they are expected to utilize the regulation's provisions in practice. While FDA has not published their main guidance document, as of this printing, it is worth mentioning that FDA has published three FSVP related guidance documents (see the links to the right).
PPT, PM	Ch. 1	18 1-13			1	Capitalized the words "Produce Safety" in sub-bullet under bullet #2.
PM	Ch. 1	1-13	PP 1	3		Add the words "known or" in front of "…reasonably foreseeable hazards…."
PPT, PM	Ch. 1	Slide 19 1-14	All	All	1	Moved previous slide 23 "FSMA Creates New Role for Importers of Food" and related text previously on page 1-18 to page 1-14.
PPT, PM	Ch. 1	Slide 20 1-14 & 1-15	All	All	2 on 1-14	Moved previous slide 22 "FSMA Implementation" and related text on pages 1-14 & 1-15. Moved the text that begins the last paragraph at the top of page 1-15 that says: "Monitoring food industry and importer

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						compliance," to become the third item in the list, making it consistent with the third sub-bullet on slide. The last paragraph at the top of page 1-15 now begins with "It needs to be emphasized…"
PPT, PM	Ch. 1	Slide 21 1-15 & 1-16	All	All	1 on 1-15	Changed slide 21 "FDA FSMA Authorities" to "Other FSMA Authorities" Added the word "a" in the last bullet on slide between the words "or" and "food." Changed the text beneath slide as noted below: In the first sentence of the last paragraph (PP 4), the words "has authority to" was added between the words "FDA" and "require." In the second sentence of the last paragraph (PP 4) the wording was changed to say: "There is no general requirement for certification as a condition of entry into the U.S." has been bolded.
PM	Ch. 1	1-16	RN			Added RN for FDA's Technical Assistance Network (TAN) that says: FDA's Technical Assistance Network (TAN) is available to answer regulatory or rule interpretation questions. TAN can be accessed at: http://www.fda.gov/fsma The FSPCA TAN is available to answer scientific/technical questions about the rule. The FSPCA TAN can be accessed at: https://www.ifsh.iit.edu/fspca/fspca-technical-assistancenetwork More information about these and other resources are available in Appendix 7.
CHAPTER 2 CHANGES						

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IG	Ch. 2	2-1	IN			Added a new IN that says: FDA wrote the FSVP rule to have maximal flexibility to accommodate different situations. Therefore, formats and templates that were common throughout the PC course instruction are generally absent in the FSVP course. We have provided example forms in Chapters 4, 5, 6, and 7, that are NOT mandatory, but can be modified to fit the importer's needs. As instructors, it is important for you to stress that importers should use their own judgement as to what decisions and documentation meet the requirements of the rule and will be acceptable to FDA.
IG	Ch. 2	2-2	RN			Changed the previous IN to RN and reworded the RN to say: Some attendees may be interested in learning about the FDA Voluntary Qualified Importer Program (VQIP). FDA anticipates accepting the first application for VQIP in January 2018. This FDA program and how an importer qualifies for the VQIP are, however, beyond the scope of this course. See Appendix 9 for the FDA VQIP fact sheet.
PM	Ch. 2	2-2	RN			Added RN that says: Some attendees may be interested in learning about the FDA Voluntary Qualified Importer Program (VQIP). FDA anticipates accepting the first application for VQIP in January 2018. This FDA program and how an importer qualifies for the VQIP are, however, beyond the scope of this course. See Appendix 9 for the FDA VQIP fact sheet.
PPT, PM	Ch. 2	Slide 4 2-3	All	All	1	Added new slide, "Purpose of the FSVP Rule." Added related text beneath slide that says: Before we discuss what an FSVP is and the purpose of FSVPs, it is important to stop for a moment to consider the overarching purpose and key principles of the FSVP rule.

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						Recognizing that producers of food for the U.S. market and importers of that food were always expected to supply food that complies with U.S. food safety requirements, the FSVP rule sets forth requirements for importers to verify that U.S. food safety standards are being met. The rule gives importers a critical role in ensuring food safety and defines importers who must fulfill these obligations in a very specific way, including that they must reside in the U.S. But we will say more about this in the next few chapters.
PM	Ch. 2	2-3	KP			Moved KP previously on page 2-4 to page 2-3.
PPT, PM	Ch. 2	Slide 5 2-4	All	All	1	Moved previous slide 4 “Key Principles of FSVP Rule” and related text previously on page 2-3 to page 2-4.
PPT, PM	Ch. 2	Slide 6 2-5	All	All	1	Added new slide 6, “What Is an FSVP?” and related text beneath slide that says: A Foreign Supplier Verification Program does not have a set format. The FSVP rule sets forth requirements that must be met, but it may be the case that only a few or many requirements pertain to your particular food/foreign supplier circumstances. What you do in implementing the FSVP requirements constitutes your program. How you document what you do is what FDA will see in assessing your compliance with the FSVP rule. Therefore, records are very important. The cumulative records demonstrating implementation of FSVP requirements are your FSVP.
PPT, PM	Ch. 2	Slide 7 2-6	All	All	1	Moved previous slide 5 “Purpose of FSVPs” and related text beneath slide, previously on 2-4, to page 2-6. Changed second sub-bullet on slide to say: Food is not adulterated under the FD&C Act or misbranded due to undeclared allergens (allergens for human food only).
PPT, PM	Ch. 2	Slide 8 2-6	All	All	2	Previous slide 6, “Who Is an “Importer” Under FSVP Rule?” and related text beneath slide, previously on 2-4.

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						Added sub-bullet to slide that says: Note that the term "U.S. owner or consignee" is also defined separately in the FSVP rule as "the person in the United States who, at the time of the U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food."
PM	Ch. 2	2-6	RN			Revised RN to say: See the 21 CFR Part 1, Subpart L, 1.500 Definitions for FSVP "importer" and "U.S. owner or consignee." Definitions are also in the Definitions and Acronyms in Appendix 10.
PPT, PM	Ch. 2	Slide 9 2-7	All	All	1	Moved previous slide 7 "Who Is an "Importer" Under FSVP Rule? (continued)" and related text beneath slide, previously on page 2-5 to page 2-7. Bolded the first sentence of text beneath slide that says: The definition also states that if there is no owner or consignee in the U.S., the foreign owner or consignee may designate a U.S. agent or representative to carry out the FSVP responsibilities. Changed "U.S. Customs entry forms" in the last sentence of second paragraph to "CBP entry filing."
PM	Ch. 2	2-7	KP			Added KP that says: Note that the definition of importer in the FSVP rule is different from other definitions that an importer may be used to, such as the "importer of record." The FSVP importer could be, but isn't necessarily, the "importer of record" for purposes of submitting entry with U.S. Customs and Border Protection (CBP). That person, who might be a customs broker or filer, might not always be a person with a financial interest in the food or have the knowledge and ability to conduct supplier verification.

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PM	Ch. 2	2-7	KP			Added KP that says: Note that throughout the course, when the FSVP importer is referred to as a "person," it means an individual, a company, or other entity.
PPT, PM	Ch. 2	Slide 10 2-8	All	All	1	Moved previous slide 8 “Determining Who Will Be the FSVP Importer” and related text beneath slide, previously on page 2-6 to page 2-8. Added a sub-bullet beneath first bullet that says: The FSVP “importer” must be someone in the U.S. and meet the definition of FSVP importer.
PM	Ch. 2	2-8	KP			Added second paragraph to KP, previously on 2-6, that says: Additional Responsibilities/Benefits: Although you will have additional responsibilities as an FSVP importer, you will also receive many benefits, such as gaining insight into the supply chain and ensuring your standards are upheld.
PM	Ch. 2	2-8	RN			Added a RN that says: To help identify who should be the FSVP importer, we have provided Workaid A: “Determining the FSVP Importer” in Appendix 3. This workaid is intended to help a person/entity, who receives/sells imported food, ensure that an appropriate FSVP importer has been designated by parties involved in the importation of the food, AND that the U.S. Customs’ filer enters that name, address, and DUNs number as the FSVP importer.
PPT, PM	Ch. 2	Slide 11 2-9	All	All	1	Moved previous slide 9 “FSVP Importer vs. Importer of Record” and related text beneath slide, previously on page 2-7 to page 2-9. Bolded the text and changed the last bullet on slide to say: The person/entity that is the FSVP importer is the person who FDA will hold accountable if FSVP requirements are not met.

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PPT, PM	Ch. 2	Slides 12 & 13; pages 2-10 & 2-11	All	All	1 on 2-10 1 on 2-11	Added new slides 12 and 13, "FSVP Importer Examples" and "FSVP Importer Examples (continued)" respectively, from the text at the bottom of previous pages 2-7 and 2-8. Example #1 and Example #2 are on new slide 12 and as text beneath slide on page 2-10. Example #3 and #4 are on new slide 13 and as text beneath slide on page 2-11. Changed the last two sentences in Example #4 to say: If the other firm owns the product when offered for entry, they are the FSVP 'importer.'" If the retailer has agreed in writing to purchase the food at the time of entry, the retailer could also be the FSVP "importer.
PPT, PM	Ch. 2	Slide 14 2-12	All	All	1	Moved previous slide 10 "Who Is a "'Foreign Supplier'?" and related text beneath slide, previously on page 2-8 to page 2-12.
PM	Ch. 2	2-12	KP			Moved both KPs previously on page 2-8 to page 2-12.
PPT, PM	Ch. 2	Slide 15 2-13	All	All	1	Moved previous slide 11 "Who Is a Qualified Individual?" and related text beneath slide, previously on page 2-10 to page 2-13. Lowercased "qualified individual" in the second bullet on slide.
PM	Ch. 2	2-13	KP			Added KP that says: The term "qualified individual" as used throughout the FSVP course is ALWAYS the FSVP definition, unless otherwise indicated (see Appendix 10: Definitions and Acronyms). The qualified individual or QI definition in the FSVP rule states that a QI must have the education, training, or experience to carry out the tasks for which he/she is responsible. FSVP qualified

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						individuals are not required to receive training under a standardized curriculum or equivalent training. Additionally, the importer may use different qualified individuals to perform different tasks.
PPT, PM	Ch. 2	Slide 16 2-14	All	All	1	Moved previous slide 12 “Required Tasks Must Be Done by a Qualified Individual” and related text beneath slide, previously on page 2-11 to page 2-14.
PPT, PM	Ch. 2	Slide 17 2-15	All	All	1	Moved previous slide 13 “How Is “Food” Defined?” and related text beneath slide, previously on page 2-12 to page 2-15. Removed the text, “and conveyor belts that contact food in food processing facilities,” from the second sentence, third paragraph, third line. Second sentence now says: Food contact substances, such as food packaging that contacts food, are regulated as a type of food additive because some of the materials used in making them migrate into food.
PM	Ch. 2	2-15	RN			Added RN that says: The definition of food comes from the FD&C Act. Refer participants to Appendix 10 for more information.
PM	Ch. 2	2-15	KP			Added KP to say: Food contact substances include packaging, ceramicware, flatware, utensils, and plates. FDA has provided a 2-year extension for importers of food contact substances to comply with the FSVP rule. See FDA Guidance regarding the extension: https://www.fda.gov/food/guidanceregulation/fsma/ucm517545.htm
PPT, PM	Ch. 2	Slide 18 2-16	All	All	1	Moved previous slide 14 “How Is “Food” Defined? (continued)” and related text beneath slide, previously on page 2-13 to page 2-16.

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						A sub-bullet was added to the first bullet that says: Most (not all) meat, poultry, certain processed egg products, or catfish (*Siluriformes spp.*), regulated by the U.S. Department of Agriculture (USDA).
PPT, PM	Ch. 2	Slide 19 2-17	All	All	1	Moved previous slide 15 “Chapter 2: Summary” and related text previously on page 2-14 to page 2-17.
PPT, PM	Ch. 2					Deleted previous slide 16 “Chapter 2: Questions.”
PPT, PM	Ch. 2	20 2-18			1	Added new slide 20 “Chapter 2 Exercise: ‘Who Is the FSVP Importer?’”
PPT	Ch. 2	Slides 21-29				Added a slide (optional) for each scenario to be used during the exercise.
CHAPTER 3 CHANGES						
PPT, PM	Ch. 3	3-1				Changed chapter title “Chapter 3: Overview of Requirements” to “Chapter 3: Overview of the Requirements”
PM	Ch. 3	3-2	PP 4	3-5		Reworded fourth paragraph to say: This chapter also contains a short overview on the “modified” requirements that apply to dietary supplements, food from “very small importers,” food from “certain small foreign suppliers,” or food from countries that FDA recognizes as having comparable food safety systems for certain foods, under Systems Recognition.
PPT, PM	Ch. 3	Slide 3 3-2			1	Changed Objective #3 to say: Identify the standard requirements.
PM	Ch. 3	3-4	PP 1	6 & 7		Reworded last sentence to say: Nevertheless, it is important to understand as an importer that—even if the food you import is exempted from FSVP—the food is still required to meet U.S. food safety standards.
PPT, PM	Ch. 3					Deleted previous slide 5 “Does FSVP Apply to My Situation?” and related text previously on page 3-4.

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PPT, PM	Ch. 3	Slide 5 3-4			1	Moved previous slide 6 "Does FSVP Apply to My Situation? (continued)" and related text previously on page 3-5 to page 3-4 and removed the word "(continued) from slide title.
PPT, PM	Ch. 3					Deleted previous slide 7 "Foods that are Exempted?" previously on page 3-5.
PPT, PM	Ch. 3	Slide 6 3-5			1	Changed title of slide to "Exempted Foods (Foods Not Covered By FSVP)" Changed bullet 3 and added 3 sub-bullets to say: • Foods not intended for sale or distribution in the U.S. and foods intended for personal use: o Food for research or evaluation (subject to certain requirements) o Food that is imported for processing and future export (no distribution in the U.S.) o Food for personal consumption Changed bullets 4 and 5 to say: • Certain meat, poultry, processed egg products (products subject to Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection Acts), and *Siluriformes spp.* fish, including catfish • Food manufactured/processed, raised, or grown in U.S., then exported and returned without further manufacturing/processing in a foreign country
PM	Ch. 3	3-5	RN			Added RN that says: FDA has provided guidance and additional information about how the FSMA rules interact with requirements for Seafood and Juice HACCP and for LACF. The guidance can be accessed at: https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm569554.htm

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PPT, PM	Ch. 3	7 3-5 & 3-6	PP 1 beneath slide	All	2	Moved previous slide 9 “Foods Under FDA HACCP Rules” and related text previously on page 3-6 to page 3-5. Reworded the first paragraph of text beneath slide to say: Several decades ago, FDA established regulations to require that a food safety controls system for juice and seafood called Hazard Analysis and Critical Control Points (HACCP). (See 21 CRP Part 120 for juice and 21 CFR Part 123 for seafood.) In addition to controls for processors, these rules imposed requirements on importers of these products. For this reason, Congress explicitly exempted these products from FSVP because importers of those products are subject to supplier verification requirements under the HACCP regulations (21 CFR 1.501(b)).
PPT, PM	Ch. 3	Slide 8 3-6 & 3-7	All	All	1	Moved previous slide 10 “Alcoholic Beverages (Certain Conditions)” and related text previously on page 3-7 to pages 3-6 and 3-7. Changed the second sub-bullet under the first bullet to say: The foreign facility is the “same type of facility as those regulated by Department of Treasury in the U.S. under the Federal Alcohol Administration Act (FAAA) (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.)”
PPT, PM	Ch. 3	Slide 9 3-7	All	All	1	Moved previous slide 11 “Foods Not Intended for Sale or Distribution in the U.S.” and related text previously on page 3-8 to page 3-7 and changed the title to “Foods Not Intended for Sale or Distribution in the U.S. and Foods Intended for Personal Use” Deleted the first bullet on slide and changed the three sub-bullets to bullets. Also switched the position of the last two bullets. The slide now says:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• Food imported for research or evaluation (subject to certain requirements) • Food that is transshipped through the U.S. or imported for further processing and export (no distribution in the U.S.) • Food imported for personal consumption Changed the first sentence to say: The FSVP rule provides for certain exemptions for certain types of food that are not for sale or distribution to the public in the U.S. and food intended for personal consumption.
PPT, PM	Ch. 3	Slide 10 3-8	All	All	1	Moved previous slide 12 “Certain Meat, Poultry, and Egg Products” and related text previously on page 3-9 to page 3-8. Changed the third bullet to say: Also applies to raw materials and ingredients imported by an importer who uses them to manufacture alcohol in the U.S.
PPT, PM	Ch. 3	Slide 11 3-8 & 3-9	All	All	2	Moved previous slide 13 “U.S. Food Exports Returned” and related text previously on page 3-9 to page 3-8. Added a sentence between sentence 2 and 3 in the paragraph beneath slide that says: If sold for consumption in the U.S., they will have to meet U.S. safety standards.
PM	Ch. 3	3-8	KP			Added KP that says: An example of a U.S. food export returned, might be a product labeled in accordance with the requirements of the foreign importing country, including that it is in the language of the importing country. If the customer rejects the product for some reason and sends it back to the U.S. manufacturer, the importer would not have to have an FSVP, but also could NOT sell it in the U.S., unless it meets all FDA requirements.

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PPT, PM	Ch. 3	Slide 12 3-9	All	All		Moved previous slide 14 “Low-Acid Canned Foods” and related text previously on page 3-10 to page 3-9 and changed the title of the slide to “Low-Acid Canned Foods—Partial Exemption for Microbiological Hazards” Changed the slide to say: • Low-acid canned foods (LACFs) are NOT exempt from FSVP • An importer of LACFs must: o Verify and document that the food was produced in accord with LACF regulations (21 CFR Part 113), which pertain to microbiological hazards. o For all hazards not controlled by part 113, the importer is required to have an FSVP. • An importer who uses raw materials or other ingredients to manufacture/process an LACF in the U.S. is: o Required to be in compliance with Part 113, and o Must have an FSVP for all other hazards or comply with the PC rules. Changed the last sentence in the second paragraph of the text beneath slide to say: In other words, an importer of raw materials who is in compliance with the LACF rule in part 113 (which addresses microbiological hazards) must still have an FSVP for all other reasonably foreseeable hazards identified by the FSVP importer, as will be discussed later.
PM	Ch. 3	3-9	RN			Added RN that says: FDA has provided guidance and additional information about how the FSMA rules interact with requirements for Seafood and Juice HACCP and for LACF. The guidance can be

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						accessed at: https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm569554.htm
PPT, PM	Ch. 3	Slide 13 3-10	All	All		Moved previous slide 15 “Foods Received and Processed by Importers Who Are Subject to PC Rules” and related text previously on page 3-11 to page 3-10. Spelled out first use of acronym CBP to say, “Customs and Border Protection (CBP)” in sub-bullet under second bullet. Bolded last sentence in first paragraph of text beneath slide that says: Therefore, to avoid redundant requirements, FDA states that, if you are a manufacturer/processor who is subject to and in compliance with the supply chain provisions of the PC rules, you are deemed to be in compliance with most of the FSVP requirements for the food you import.
PPT, PM	Ch. 3	Slide 14 3-11	All	All	1	Moved previous slide 16 “FSVP Standard Requirements” and related text previously on page 3-12 to page 3-11. Changed bullet 7 to say: Reevaluate foreign supplier (at least every three years or when there is a reason to do so). Changed the text beneath slide to say: Each of the FSVP standard requirements are covered in detail in Chapters 4 through 9. The concepts are just being introduced here. If you go to Appendix 3, Workaid C, in your manual, you will see the “Summary of FSVP Requirements.” This summary covers the steps we will be going over in Chapters 4-9, and can be used as a quick reference in the future.

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PPT, PM	Ch. 3					Deleted previous slides 17-26 and related text previously on pages 12-19.
PPT, PM	Ch. 3	Slide 15 3-11 & 3-12	All	All		Moved previous slide 27 “When Do Modified Requirements Apply?” and related text previously on pages 3-20 & 21 to pages 3-11 & 3-12. Changed slide text to say: • If you are a “Very Small Importer” • If the imported food is from “Certain Small Foreign Supplier(s)” • If the imported food is from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” for certain foods under Systems Recognition • If you import dietary supplements or dietary supplement components (see Appendix 4) • More information on eligibility is introduced during the “Review: Questions About FSVP Requirements,” later in this chapter, and is covered more fully in Appendix 5. Bolded first paragraph that says: Generally, modified FSVP requirements are aimed at smaller entities or products falling under a discrete or distinctive regulatory framework. Modified requirements may require less or different FSVP process steps than the “standard” requirements. Persons/companies that may be eligible for modified requirements may still choose to follow the “standard” FSVP requirements. Changed the second and third paragraphs of text beneath slide (top of new page 12) to say: Modified FSVP requirements apply if you are a “very small importer”; if you are importing food from “certain small foreign

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						suppliers" (21 CFR 1.512(a)); if the food you are importing is from foreign supplier(s) in countries with food safety systems recognized by FDA as "comparable" for certain foods under Systems Recognition; and finally, modified requirements apply if you import dietary supplements or dietary supplement components (see Appendix 4). We will cover the eligibility criteria of the first three situations in more detail in the next few slides. For more information regarding "FSVP Modified Requirements," see Appendix 5.
PM	Ch. 3		KP			Added KP that says: More details regarding modified requirements eligibility and the specific requirements are provided in Appendix 5, but in general, Importers who are eligible for the modified requirements do not have to perform the standard hazard analysis, evaluation of the supplier, or verification activities. However, they still must have a modified FSVP program that includes: • Documentation of eligibility; • Use of a qualified individual for each activity; • Identification of the FSVP importer at entry; and Obtaining written assurance, before importing the food and at least every 2 years thereafter, that their foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the section 418or 419 of the FD&C Act (if applicable) and is producing the food in compliance with section 402 (adulteration) and 403(w) (allergen labeling, if applicable).
PPT, PM	Ch. 3	Slide 16 3-12 & 3-13	All	All	1	Moved previous slide 28 "What Is a "Very Small Importer"?" and related text previously on page 3-21 to pages 3-11 & 3-12.

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						Inserted a sentence in the second paragraph, between the first sentence and the last sentence that says: FDA has published charts to help with this: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm
PPT, PM	Ch. 3	Slide 17 3-13	All	All	1	Moved previous slide 29 "What Are "Certain Small Foreign Suppliers"?" and related text previously on page 3-23 to page 3-13. Added quote marks to the text "qualified facility" in the first sub-bullet. Changed sub-bullet 2 to say: • You are importing produce from a foreign supplier that is a farm that grows produce and is not a "covered farm" under the Produce Safety rule (i.e., annual monetary value of produce sold is < U.S. $25,000) or satisfies the Produce Safety Rule requirements for a "qualified exemption," or…
PPT, PM	Ch. 3	Slide 18 3-14	All	All	1	Moved previous slide 30 "When Food Is Produced Under a Food Safety System Recognized by FDA" and related text previously on page 3-23 to page 3-14. Changed slide to say: • If you import foods from a foreign supplier in a country with food safety systems recognized by FDA as "comparable" for certain foods under Systems Recognition, your requirements can be reduced if: o The food is within the scope of the Systems Recognition arrangement; o Your supplier is under the regulatory oversight of that food safety authority; and o The supplier must be in good compliance standing.

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						• If these conditions are met, you are not required to, among other things: o Perform a hazard analysis, or o Conduct a foreign supplier evaluation for approval and verification. Changed second sentence in the first paragraph of the text beneath slide to say: Currently, New Zealand's, Canada's, and Australia's systems have been recognized as comparable for certain foods under Systems Recognition. Information on the Australia's recognition with links to the evaluation process can be found on the FDA website at: https://www.fda.gov/food/newsevents/constituentupdates/ucm553382.htm Changed the second paragraph of the text beneath slide to say: If FDA officially recognizes that another country's food safety system is comparable for certain foods under Systems Recognition, and if your foreign supplier is providing food that is within the scope of that official recognition and under the jurisdiction of the government authority responsible for that food safety system—you, as the FSVP importer of food from the foreign supplier, are not required to: 1. Perform a hazard analysis, or 2. Conduct a foreign supplier evaluation for approval and verification.
PM	Ch. 3	3-14	KP			Added KP that says: Currently, the food safety systems of New Zealand, Canada, and Australia have been recognized as having a comparable food safety system for certain foods under Systems Recognition.

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PPT, PM	Ch. 3	Slide 19 3-15	All	All	1	Moved previous slide 31 "When Food Is Produced Under a Food Safety System Recognized by FDA (continued)" and related text previously on page 3-24 to page 3-15. Changed the text of sub-bullet 4, under the first bullet, from "U.S. Customs documents at entry" to "CBP entry filing."
PPT, PM	Ch. 3	Slide 20 3-16	All	All	1	Moved previous slide 32 "Determine the Food Safety Requirements that Apply to Your Supplier" and related text previously on page 3-25 to page 3-16.
PPT, PM	Ch. 3	Slide 21 3-17	All	All	1	Moved previous slide 33 "Determine the Food Safety Requirements that Apply to Your Supplier (continued)" and related text previously on page 3-26 to page 3-17.
PM	Ch. 3	RN				Added RN that says: We will be providing a short Preventive Controls and Produce Safety Session next, as part of this course. Additionally, more information can be found in Appendix 6a and 6b of this manual, which are overviews of the Preventive Controls and Produce Safety rules respectively.
PPT, PM	Ch. 3	Slide 22 3-17	All	All	2	Moved previous slide 34 "Examples of Other Food Safety Requirements That May Apply to Food You Import" and related text previously on page 3-26 to page 3-17. Added text as the first sub-bullet that says: • Low-acid canned foods (LACF) – 21 CFR part 113
PPT, PM	Ch. 3	Slide 23 3-18	All	All	1	Moved previous slide 35 "The Importance of Communications with Your Supply Chain" and related text previously on page 3-27 to page 3-18.
PPT, PM	Ch. 3	Slide 24 3-19	All	All	1	Moved, edited, and combined previous slides 36 and 37, "Review: Questions About FSVP Requirements" and "Review: Questions About FSVP Requirements (continued)"

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						respectively, and related text previously on page 3-28 to page 3-19. Changed the second bullet to say: In approaching the following slides, think of a specific food that you import, before starting to go through the questions, and see how FSVP might apply to your specific situation. Added a third bullet that says: The questions are also located in the Exercise Workbook, Chapter 3, page 7. Added two paragraphs beneath slide that say: In approaching the following slides, think of a specific food that you import, before starting through the questions, and see how FSVP might apply to your specific situation. If desired, you can enter your answers to the questions in the Exercise Workbook (see Chapter 3, page 7). Note: If you have any confusion about the algorithm questions, now is the time to clear up that confusion before we go further. So, raise your hand. If your question pertains to a topic that requires a lengthy explanation and is covered in a later chapter, we might ask you to wait for the full answer.
PPT, PM	Ch. 3	Slide 25 3-20	All	All	1	Moved previous slide 38 “Question 1” and related text previously on page 3-29 to page 3-20. Changed the “NO” answer on slide and in the text below to say: • **NO:** FSVP does not apply to you for this food.
PPT, PM	Ch. 3	Slide 26 3-21	All	All	1	Moved previous slide 39 “Question 2” and related text previously on page 3-30 to page 3-21.

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PPT, PM	Ch. 3	Slide 26 3-21	All	All	1	Moved previous slide 39 “Question 2” and related text previously on page 3-30 to page 3-21.
PPT, PM	Ch. 3	Slide 27 3-22	All	All	1	Moved previous slide 40 “Question 2 (continued)” and related text previously on page 3-31 to page 3-22. Changed “YES” answer on slide and in the text below to say: • **YES:** FSVP does not apply to you for this food.
PPT, PM	Ch. 3	Slide 28 3-22	All	All	2	Moved previous slide 41 “Question 3” and related text previously on page 3-31 to page 3-22.
PPT, PM	Ch. 3	Slide 29 3-23	All	All	1	Combined and edited previous slides 42 and 43, “Question 4” and “Question 4 (continued)” respectively, “Question 4” and moved the slide and related text previously on page 3-32 to page 3-23. Changed first bullet to say: • Are you an importer subject to the preventive controls regulation for human or animal food, a food processor/manufacturer receiving the imported food, and in compliance with one of the following requirements in 21 CFR parts 117 or 507? o (1) You implement preventive controls for the hazards in the food in accordance with either of the Preventive Controls rules; o (2) You are not required to implement a preventive control under either of the preventive controls rules; or o (3) You have established and implemented a risk-based supply-chain program in compliance with either of the preventive controls rules. Changed the paragraph beneath slide to say:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• Are you an importer subject to the preventive controls regulation for human or animal food, a food processor/manufacturer receiving the imported food, and in compliance with one of the following requirements in 21 CFR parts 117 or 507? o (1) You implement preventive controls for the hazards in the food in accordance with either of the Preventive Controls rules; o (2) You are not required to implement a preventive control under either of the preventive controls rules; or o (3) You have established and implemented a risk-based supply-chain program in compliance with either of the preventive controls rules. o If your answer is:
PPT, PM	Ch. 3	Slide 30 3-24	All	All	1	Moved previous slide 43 “Question 5” and related text previously on page 3-33 to page 3-24.
PPT, PM	Ch. 3	Slide 31 3-25	All	All	1	Moved previous slide 44 “Question 6” and related text previously on page 3-34 to page 3-25.
PPT, PM	Ch. 3	Slide 32 3-25	All	All	2	Moved previous slide 45 “Question 6 (continued)” and related text previously on page 3-34 to page 3-25.
PPT, PM	Ch. 3	Slide 33 3-26	All	All	1	Moved previous slide 46 “Question 7” and related text previously on page 3-35 to page 3-26.
PPT, PM	Ch. 3	Slide 34 3-27	All	All	1	Moved previous slide 47 “Question 8” and related text previously on page 3-36 to page 3-27. Changed the first bullet to say: Do you import a food that is not intended for further manufacturing/processing before consumption from a country that is officially recognized by FDA as having a food safety

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						system that is comparable for certain foods under Systems Recognition? Changed the "YES" answer to say: • **YES:** You may be subject to modified FSVP requirements for food from those countries if the food is under the regulatory oversight of the food safety authority, the food is within the scope of the recognition agreement, and the supplier is in good compliance standing with the relevant food safety authority in that country. Changed the first paragraph beneath slide to be consistent with slide changes: Do you import a food that is not intended for further manufacturing/processing before consumption from a country that is officially recognized by FDA as having a food safety system that is comparable for certain foods under Systems Recognition? (See 21 CFR 1.513) Added a second paragraph that says: We note that currently there are only three countries that have been officially recognized by FDA and those are New Zealand (2012), Canada (2016), and Australia (2017). Changed the "YES" answer to be consistent with slide changes: **YES:** You may be subject to modified FSVP requirements for food from those countries if the food is under the regulatory oversight of the food safety authority, the food is within the scope of the recognition agreement, and the supplier is in good compliance standing with the relevant food safety authority(ies) in that country).
PPT, PM	Ch. 3	Slide 35 3-28	All	All	1	Moved previous slide 48 "The Final Answer" and related text previously on page 3-37 to page 3-28.

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PPT, PM	Ch. 3	Slide 36 3-28 & 3-29	All	All	2	Moved previous slide 49 “Chapter 3: Summary” and related text previously on page 3-37 to page 3-28 & 3-29. Deleted previous slide 50 “Chapter 3: Questions”
PPT, PM	Ch. 3	Slide 37 3-29	All	All	1	Added new slide 37 “Chapter 3 Exercise: “Does FSVP Apply to These Food Products?” that says: **Slide:** • Timing: 30 minutes total o 10 minutes working in table groups o 20 minutes reporting out and discussing • Directions: In your group, read the example food products listed in the table (see Exercise Workbook, Chapter 3, page 10). o Discuss whether or not FSVP standard requirements or modified requirements apply or if the food is exempt. o The instructor will call upon each group to put your answers on the table displayed on the projector screen (next slide). Added text beneath slide that says: This exercise provides you with the opportunity to practice determining whether FSVP standard requirements or modified requirements apply to a specific food product or if the food product is exempt. **Directions:** In your group, read the example food products listed in the Imported Food Product table in the Exercise Workbook (see Chapter 3, page 10). Identify whether FSVP standard requirements apply, modified requirements apply, or if the food is exempt for each food product. The group will be called upon by the instructor to put a sticky note in the “correct” box projected on the slide screen in front

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						of the class. The sticky note should have each group's name or number.
PCPS SESSION CHANGES						
PPT, PM	PCPS					Changed chapter title "PCPS Session: Preventive Controls and Produce Safety Session" to "PCPS: Preventive Controls and Produce Safety Session"
PM	PCPS	PCPS-1	RN			Added RN that says: This session is intended to provide a brief overview of the other major FSMA rules that are relevant to the verification responsibilities of importers. While we don't have time to answer the questions you are likely to have as we go through this session, Appendix 6a and 6b of your manual provide more detailed overviews. Also, remember that these other rules are the subject of separate courses that you can take, if desired. **PC for Human Food rule:** https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm **PC for Animal Food rule:** https://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm **Produce Safety rule:** https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm
PPT, PM	PCPS	Slide 3 PCPS-2			2	Changed "(CGMPs)" in Objective 1 to "(CGMP)" and throughout the rest of the slides/text. Changed "CGMPs" in Objective 2 to "CGMP)" and throughout the rest of the slides/text.
PPT, PM	PCPS	Slide 5 PCPS-4			1	Changed slide 5 "PC for Human Food Rule Key Requirements" to say:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• Two of the main requirements of the PC rule for human food are: o CGMP updated for human food production o Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes: ▪ Hazard analysis ▪ Preventive controls ▪ Oversight and management of preventive controls (monitoring, corrective actions and corrections, and verification) ▪ Supply-chain program ▪ Recall plan
PM	PCPS	PCPS-4	PP 1	2 & 3		Changed the second sentence to say: The PC for human food rule updates the CGMP as basic prerequisite requirements for producing safe food.
PPT, PM	PCPS	Slide 6 PCPS-5			1	Changed slide 6 “PC for Animal Food Rule Key Requirements” to say: • Two of the main requirements of the PC rule for animal food are: o CGMP established for animal food production. o Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes: ▪ Hazard analysis

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						▪ Preventive controls ▪ Oversight and management of preventive controls (monitoring, corrective actions and corrections, and verification) ▪ Supply-chain program ▪ Recall plan
PPT, PM	PCPS	Slide 7 PCPS-5 & PCPS-6	All	All	2	Added new slide 7 “Who Is Covered by the Produce Safety Rule?” that says: • Covered Produce: o Certain produce that are fruits and vegetables (including sprouts, mushrooms, and certain nuts) that are: ▪ “Raw Agricultural Commodities” (RACs) grown domestically or will be offered for import into any state or territory of the United States • Covered Farms and Farm Definition: o Primary Production Farms o Secondary Activities Farms Added new text beneath slide that says: The Produce Safety rule applies to covered produce, including certain fruits and vegetables (including sprouts, mushrooms, and certain nuts) that are Raw Agricultural Commodities (RACs). This includes a produce RAC that is grown domestically or will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. It does not apply to some types of produce, as explained below. Requirements for the growing and handling of fresh sprouts are also covered by the Produce Safety rule, in Subpart M. Those requirements are beyond the scope of this chapter and will not be mentioned further. Beyond the type of food, the regulation only applies to operations that are “covered farms” that handle

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						covered produce (i.e., does not apply to dairy or wheat farms that do not grow, harvest, or handle covered produce). FDA defines two types of operations as farms: A Primary Production Farm and a Secondary Activities Farm.
PPT, PM	PCPS	Slide 8 PCPS-6	All	All	1	Moved previous slide 7 "Who Is Covered by the Produce Safety Rule?" and related text previously on page PCPS-5 to page PCPS-6 and changed title of slide to "Who Is Covered by the Produce Safety Rule? (continued)."
PPT, PM	PCPS	Slide 9 PCPS-7	All	All	1	Moved previous slide 8 "Who Is Covered by the Produce Safety Rule? (continued)" and related text previously on page PCPS-6 to page PCPS-7. Added the text "for human food" in last sentence to say: But, if more than 50% of the RACs handled by the operation are grown by non-owners then the operation is not a farm and most likely will need to comply with the PC for human food rule.
PPT, PM	PCPS	Slide 10 PCPS-8	All	All	1	Moved previous slide 9 "Produce Exempt from Produce Safety or Subject to Modified Requirements" and related text previously on page PCPS-7 to page PCPS-8. Changed slide to say: • Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management • Produce from a farm with less than or equal to $25,000 average annual sales of produce • Produce that is rarely consumed raw (see Key Point) • Produce from a farm or farm mixed-type facility with less than $500,000 average annual sales of food and a majority sold directly to qualified end-users Changed third and fourth sentence in paragraph 1 to say:

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						Likewise, produce from a farm with less than or equal to $25,000 average annual sales of produce (over the previous 3-year period on a rolling basis and adjusted for inflation) is also not covered by the rule. Produce that is identified by FDA in the rule as rarely consumed raw is not covered by the rule regardless of the size of the farm. Changed the last sentence in paragraph 4 to say: The Produce Safety rule defines a qualified end-user as the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm that produced the food, or not more than 275 miles from the farm.
PPT, PM	PCPS	Slide 11 PCPS-9	All	All	1	Moved previous slide 10 “Produce Exempt from Produce Safety or Subject to Modified Requirements (continued)” and related text previously on page PCPS-8 to page PCPS-9.
PPT, PM	PCPS					Deleted previous slide 11 “Produce Safety Rule Key Requirements” and related text.
PPT, PM	PCPS	Slide 12 PCPS-10	All	All	1	Added new slide 12 “What Is Required by the Produce Safety Rule?” that says: **Potential Routes of Contamination** • Minimize hazards from: o Agricultural water o Domesticated and wild animals o Biological soil amendment of animal origin o Health and hygiene o Equipment, tools, buildings and sanitation o Growing, harvesting, packing, and holding activities Added new text beneath slide that says:

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						The Produce Safety rule, focuses on biological hazards and specifically defined hazard as any biological agent that has the potential to cause illness or injury in the absence of its control. FDA concluded that physical hazards that can cause injury and chemical hazards, such as from crop protection chemicals, rarely occur at levels that pose a risk of serious adverse health consequences or death for individuals that would consume the product, citing an analysis of scientific literature and recall data. Therefore, the rule focuses on potential microbiological hazards. FDA identified major routes of contamination on farms and finalized requirements in certain areas, including agricultural water; domesticated and wild animals; biological soil amendments of animal origin and human waste; health and hygiene; equipment, tools, buildings, and sanitation; and growing, harvesting, packing, and holding activities. For more information on each of these you can review the Produce Safety Overview in Appendix 6.
PM	PCPS	PCPS-10	RN			Moved RN previously on page PCPS-9 to PCPS-10.
PPT, PM	PCPS	Slide 13 PCPS-11	All	All	1	Moved previous slide 12 “How Does This Relate to FSVP?” and related text previously on page PCPS-10 to page PCPS-11. Changed slide to say: • You will need to identify whether or not your foreign supplier is required to comply with: o PC for Human Food o PC for Animal Food o Produce Safety • If your foreign supplier is required to comply, you must evaluate them and perform verification activities to assure that they are producing food that provides the same level of public health protection as these rules.

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						• Keep in mind that you also need to consider what other FDA food safety requirements apply to the foods that you import in determining and performing verification activities (e.g., low-acid canned foods (LACF), infant formula) Changed text beneath slide to say: As stated earlier, this brief session is intended to let you know which of your suppliers must comply with the PC and Produce Safety rules. If you import food from these suppliers, you will have to verify that it is produced under the same level of public health protection as domestically produced food. You need to know something about these rules as you may be talking to your foreign supplier in order to satisfy FSVP requirements. Much of what your foreign supplier needs to do to satisfy the aims of the PC rules or Produce Safety rule will be useful to you in meeting your FSVP requirements. Keep in mind that you will also need to consider what other FDA food safety requirements apply to the foods you import when determining and conducting verification activities. For instance, FDA has additional requirements that must be considered beyond the PC rule for low-acid canned food or infant formula.
PPT, PM	PCPS	Slide 14 PCPS-12	All	All	1	Moved previous slide 13 “Preventive Controls and Produce Safety Session: Summary” and related text previously on page PCPS-11 to page PCPS-12.
PPT, PM	PCPS	Slide 15 PCPS-12	All	All	2	Moved previous slide 14 “Preventive Controls and Produce Safety Session: Questions” and related text previously on page PCPS-11 to page PCPS-12.
CHAPTER 4 CHANGES						
PM	Ch. 4	4-3	PP 1	3		Added the text “significantly minimize or” between the words “to” and “prevent”

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PPT, PM	Ch. 4	Slide 5 4-3			2	Removed the note at bottom of slide that said: Note: Dangerously high or low amounts of required nutrients in human or animal foods intended as a sole source of nutrition may also constitute "hazards," e.g., animal food and infant formula.
PM	Ch. 4	4-4	PP 3	6 & 7		Corrected the name of the Intentional Adulteration rule to say: Mitigation Strategies to Protect Food Against Intentional Adulteration"
PPT, PM	Ch. 4	Slide 9 4-6			1	Changed last bullet on slide to say: Nutrient deficiencies and toxicities (animal food) (1.504(b)(1)(ii))
PPT, PM	Ch. 4	Slide 11 4-7	PP 4	All	1	Removed images of RFR and Bad Bug Book Web pages. Added a third sub-bullet "FDA Import Alerts"
PM	Ch. 4	4-7	RN			Added RN that says: Links to the FDA Reportable Food Registry, FDA Bad Bug Book, and FDA Import Alerts page are available below and in Appendix 7: Technical Assistance and Resources. FDA Reportable Food Registry (RFR): https://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm FDA Bad Bug Book: https://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ FDA Import Alerts: https://www.fda.gov/forindustry/importprogram/actionsenforcement/importalerts/default.htm#list
PM	Ch. 4	4-8	RN			Added RN that says: Links to FDA Guidance Documents on Hazards are available in Appendix 7: Technical Assistance and Resources.
PPT, PM	Ch. 4	Slides 13 & 14	All	All	1 & 2	Added new slides 13 and 14 "Preventive Controls Human Food Guidance—Appendix 1—Biological Hazards Tables"

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		4-9 & 4-10				and “Preventive Controls Human Food Guidance—Appendix 1—Chemical Hazards Tables,” respectively. Added text beneath each slide to say: Slide 13: The image on the slide above is taken from the first page of the biological hazards tables within the Preventive Controls Human Food Guidance document. It provides information as to what biological hazards may be found within a specific category of food product. Slide 14: The image on the slide above is taken from the first page of the chemical hazards tables within the Preventive Controls Human Food Guidance document. It provides information as to what chemical hazards may be found within a specific category of food product. We will take a closer look at some of the potential biological, chemical, and physical hazards in the next few slides.
PPT, PM	Ch. 4	Slide 15 4-10	All	All	1	Moved previous slide 14 “Potential Biological Hazards” to slide 15 on page 4-10. Changed slide to say: • Microorganisms in foods may include: o Bacteria o Viruses o Protozoa o Yeasts o Molds • Most microorganisms in food do not cause disease in humans or animals, but some do.
PPT, PM	Ch. 4	Slide 16 4-11	All	All	1	Moved previous slide 13 “Biological Agents Cause Most Outbreaks” and related text previously on page 4-9 to page 4-11.

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PPT, PM	Ch. 4	Slide 17 4-12	All	All	1	Moved previous slide 15 Potential Chemical Hazards" and related text previously on page 4-10 to page 4-12. Added second sub-bullet under the second bullet to say: • Cleaning and sanitizing chemicals Changed the third bullet and the sub-bullet to say: • Others unintentionally present o Industrial chemicals, heavy metals, radionuclides
PM	Ch. 4	4-12	RN			Moved RN previously on page 4-11 to page 4-12.
PPT, PM	Ch. 4	Slide 18 4-13	All	All	1	Moved previous slide 16 "Undeclared Food Allergens Are Common" and related text previously on page 4-12 to page 4-13. Enlarged and bolded the text on pie chart to make it more readable.
PPT, PM	Ch. 4	Slide 19 4-14	All	All	1	Moved previous slide 17 "Food Allergy" and related text previously on page 4-13 to page 4-14.
PPT, PM	Ch. 4	Slide 20 4-15	All	All	1	Moved previous slide 18 "Potential Physical Hazards" and related text previously on page 4-14 to page 4-15.
PM	Ch. 4	4-15	KP			Added KP that says: Note that physical adulterants such as hair, insects, and dirt may contaminate food but not be injurious to health. Thus, they may not constitute a hazard per se. Nevertheless, such physical adulterants may be indicators of insanitary conditions in the manufacture, handling, or storage of food and, therefore, indicate that chemical or biological hazards also could be present in the food. Of course, very high levels of physical contaminants like hair, insects, and dirt may by themselves be considered a hazard.

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PPT, PM	Ch. 4	Slide 21 4-16	All	All	1	Moved previous slide 19 “Economically Motivated Hazards” and related text previously on page 4-15 to page 4-16. Changed third bullet to say: • Focus should be on “known or reasonably foreseeable” hazards that may arise from economically motivated adulteration.
PPT, PM	Ch. 4	Slide 22 4-17	All	All	1	Moved previous slide 20 “Who Must Perform My Hazard Analysis?” and related text previously on page 4-16 to page 4-17.
PPT, PM	Ch. 4	Slide 23 4-18 & 4-19				Moved previous slide 21 “What Hazard Analysis Must I Conduct?” and related text previously on page 4-17 to pages 4-18 & 4-19. Changed the first line of the first bullet to say: • Your qualified individual under the FSVP rule must… Changed the sub-bullet under the third bullet to say: • For example, even if the hazard analysis results in no hazard requiring a control, this conclusion and the performance of the hazard analysis must be documented still.
PPT, PM	Ch. 4	Slide 24 4-19	All	All	1	Moved previous slide 22 “Associating Hazards with Different Types of Food” and related text previously on page 4-18 to page 4-19.
PPT, PM	Ch. 4	Slide 25 4-20	All	All	1	Moved previous slide 23 “Identifying Hazards for Each Food” and related text previously on page 4-19 to page 4-20.
PPT, PM	Ch. 4	Slide 26 4-21	All	All	1	Moved previous slide 24 “Identified Hazards Must Be Evaluated” and related text previously on page 4-20 to pages 4-21. Corrected the last bullet to say:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• The evaluation of the identified hazards helps you assess the consequences of not having a control for those hazards.
PPT, PM	Ch. 4	Slide 27 4-22	All	All	1	Moved previous slide 25 “Identified Hazards Must Be Evaluated (continued)” and related text previously on page 4-21 to page 4-22.
PPT, PM	Ch. 4	Slide 28 4-23	All	All	1	Moved previous slide 26 “What Must Be Considered in a Hazard Evaluation?” and related text previously on page 4-22 to page 4-23.
PPT, PM	Ch. 4	Slide 29 4-24	All	All	1	Moved previous slide 27 “What Must Be Considered in a Hazard Evaluation? (continued)” and related text previously on page 4-23 to page 4-24.
PPT, PM	Ch. 4	4-24	KP			Moved KP previously on page 4-23 to page 4-24. Added the text “significantly minimizing” between the words “is” and “controlling…” Added a second sentence that says: This will be discussed in more detail in Chapter 5: Evaluating the Foreign Supplier’s Performance and Food Risk.
PPT, PM	Ch. 4	Slide 30 4-25	All	All	1	Moved previous slide 28 “How Will You Know About These Factors?” and related text previously on page 4-24 to page 4-25. Removed reference “(FDA response to comment 115, 80 FR 74267)” under quote on slide. Changed beginning of first sentence of text beneath slide to say: Clearly, a Preventive Controls qualified individual…

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PPT, PM	Ch. 4	Slide 31 4-26	All	All	1	Moved previous slide 29 “The Importance of Site-Specific Information” and related text previously on page 4-25 to page 4-26.
PPT, PM	Ch. 4	Slide 32 4-27	All	All	1	Moved previous slide 30 “Reviewing Another Entity’s Hazard Analysis” and related text previously on page 4-26 to page 4-27.
PPT, PM	Ch. 4	Slide 33 4-27	All	All	2	Moved previous slide 31 “Reviewing Another Entity’s Hazard Analysis (continued)” and related text previously on page 4-26 to page 4-27.
PPT, PM	Ch. 4	Slide 34 4-28	All	All	1	Moved previous slide 32 “Hazards in Produce” and related text previously on page 4-27 to page 4-28.
PPT, PM	Ch. 4	Slide 35 4-29	All	All	1	Moved previous slide 33 “What If No Hazards Require a Control?” and related text previously on page 4-28 to page 4-29. Changed the list item 1 in the text beneath slide to say: 1. You are not required to conduct an evaluation for the purpose of foreign supplier approval and verification, and Changed the last paragraph to say: Note: Remember that importers of RACs covered by the produce rule will still need to conduct verification activities for biological hazards, even if they do not identify any chemical or physical hazards.
PPT, PM	Ch. 4	Slide 36 4-30	All	All	1	Moved previous slide 34 “Hazard Analysis Process in Brief” and related text previously on page 4-29 to page 4-30.
PPT, PM	Ch. 4	Slide 37 4-30 & 4-31	All	All	2	Moved previous slide 35 “Hazard Analysis Format Examples” and related text previously on page 4-29 to pages 4-30 & 4-31 and changed title to “Example of a Preventive Controls Hazard Analysis Form.”

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						Changed the text beneath slide (top of page 4-31) to say: The Preventive Controls (PC) hazard analysis form example on the slide relates to the hazard analysis process for products that are governed by the PC rule for human foods. It is included here to illustrate a systematic approach to conducting a hazard analysis and to provide a means of comparing some of the differences between the PC hazard analysis and an FSVP hazard analysis shown on the slide below.
PPT, PM	Ch. 4	Slide 38 4-31	All	All	1	Added new slide 38 “Example of an FSVP Hazard Analysis Form” that includes a screenshot of new “Workaid D: FSVP Hazard Analysis Form Example.” Added new text beneath slide that says: The FSVP hazard analysis form example on the slide relates to the hazard analysis process for food that is imported and is governed by the FSVP rule. The format is not mandatory under the rule, but it is an example of a format that importers might use when performing a hazard analysis as part of the FSVP. The form could be modified as needed to fit many of the situations that you may face.
PPT, PM	Ch. 4	Slide 39 4-32	All	All	1	Moved previous slide 36 “Chapter 4: Summary” and related text previously on page 4-30 to page 4-32.
PPT, PM	Ch. 4					Deleted previous slide 37 “Chapter 4: Questions.”
PPT, PM	Ch. 4	Slide 40 4-33	All	All	1	Added new slide 40 “Chapter 4 Exercise: “Identify ‘Known or Reasonably Foreseeable’ Hazards” that says: • Timing: 45 minutes total o 5-10 minutes to obtain examples (2-3 examples) and describe process for each example.

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						o 35-40 minutes to identify any “known or reasonably foreseeable” hazards for each example. • Directions: o Review the example. o Use two or three examples of food products imported by participants for the exercise. o Describe the process each example food product goes through to be sure everyone has an understanding of the potential hazards. o Walk-through identifying any “known or reasonably foreseeable” biological, chemical, and physical hazards. *Note: This exercise is NOT a hazard analysis; it is only one step within the hazard analysis. The goal of the exercise is to identify "known or reasonably foreseeable” hazards.* Added text beneath slide that says: This exercise will provide you with the opportunity to practice identifying “known or reasonably foreseeable” food safety hazards for specific food products. Directions: The instructor will review the example with the class and then will ask for two to three examples from the participants to use in the exercise. The participants or the instructor, as appropriate, will describe the process the food goes through. The class will walkthrough identifying the “known or reasonably foreseeable” food safety hazards for each example.
PPT, PM	Ch. 4	Slide 41 4-34	All	All	1	Added new slide 41 “Identify ‘Known or Reasonably Foreseeable’ Hazards Exercise Example” that has the Pumpkin Seeds example.

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						Corrected the "Pumpkin Seeds" example by moving "mycotoxins/natural toxins" from the "Biological" row to the "Chemical" row. Added text beneath slide that says: This slide is an example of what the class will be doing during the exercise. During the whole group exercise, you may want to go to the Exercise Workbook, Chapter 4, starting on page 12, where there are tables for each example the class will be working through.
CHAPTER 5 CHANGES						
PM	Ch. 5	5-2	PP 3	All		Bolded last paragraph of the text beneath slide.
PM	Ch. 5	5-4	PP 1	1		Changed first sentence of text at top of page to say: "Approval of your foreign supplier will be based on your food hazard analysis,…"
PPT, PM	Ch. 5	Slide 7 5-5	All	All	1	Changed slide 7 "Hazard Analysis and Who Controls the Hazard" to say: • The hazard analysis and who is controlling the hazard must be considered when evaluating the foreign supplier's performance. • Note that when the hazard is being controlled after importation, there is no need to do an evaluation of the supplier's performance. Changed the text beneath slide to say: You, as the FSVP importer, must consider the nature of the hazards requiring a control, recognizing that different types of hazards from different sources need to be dealt with in different ways. Your FSVP must focus on those hazards requiring a control, and who is responsible for their control (there may be more than one party responsible for the hazard's control)—whether they are being controlled by your

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						foreign supplier, or, for example, your foreign supplier's supplier. As explained further in Chapter 6, there are modified requirements in 1.507 when the hazard is being controlled after importation into the U.S. In that case, there is no need to do an evaluation under 1.505. How do you do this? Well, let's look at an example.
PPT, PM	Ch. 5	Slide 8 5-6	All	All	1	Changed title of slide 8 to "Example: A Hazard Requiring a Control" Changed the slide bullets to say: • You wish to import dried navy beans. • Your supplier processes many types of beans such as pinto beans, great northern beans, soy beans, adzuki beans, and cannellini beans. • You recognize that soy is an allergen and are concerned that your dried navy beans might be susceptible to cross-contact with this allergen. • You need to verify that your supplier is effectively preventing allergen cross-contact, prior to approval of your foreign supplier. Changed the text beneath slide to say: Let's say that your foreign supplier regularly ships dried navy beans to you. The foreign supplier also processes other beans, including soy beans. Your job is to verify that the foreign supplier is implementing controls to significantly minimize or prevent allergen cross-contact from the soy beans throughout the process within the manufacturing facility. Your foreign supplier may apply a variety of controls, for example:
PPT, PM	Ch. 5	Slide 9 5-6	All	All	2	Added new slide 9 "Allergen Control Procedures" that says: • Scheduling protocols • Clean-out procedures • Change-out procedures

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• Personnel practices • Transportation practices • Procedures for allergen testing in critical process area Added text beneath slide that says: Multiple preventive controls for the soy hazard can fall into various types of preventive controls, as illustrated in this slide. The need for allergen controls was determined through the hazard analysis process. The allergen control practices depend on who is implementing the control, the product, and manufacturing practices.
PPT, PM	Ch. 5	Slide 10 5-7	PP 3	All	1	Changed slide 10 “Foods That Cannot Be Consumed Without an Appropriate Control” to say: • When a food has a hazard, but it is the type of food that cannot be consumed without application of an appropriate control: • You are not required to: o Conduct an evaluation of a foreign supplier performance, nor o Perform supplier verification activities for that hazard. • You must: o Document your determination that the food falls into this category. o Perform a supplier verification for other hazards (see Chapter 6). • For example, consumers aren’t expected to eat raw coffee beans because beans are normally roasted before consumers consume them, which would address the reasonably foreseeable hazards. Changed the third paragraph in the text beneath slide to say:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						You must also document your determination that the food could not be consumed without application of an appropriate control.
PM	Ch. 5	5-7	KP			Added KP that says: Although produce that is rarely consumed raw is not covered by the Produce Safety regulation (see 21 CFR 112.2(a)(1)), importers of such produce will need to determine whether it has any chemical or physical hazards requiring a control. If produce rarely consumed raw has a chemical or physical hazard that is to be controlled before importation, the importer will need to conduct supplier evaluation, approve the supplier, and perform supplier verification activities under sec. 1.505 and sec. 1.506. If the importer relies on its customer or a subsequent entity in U.S. distribution to control the hazard, the importer will need to comply with sec. 1.507.
PPT, PM	Ch. 5	Slide 11 5-8	All	All	1	Added new slide 11 “Group Exercise: Who Is Controlling the Biological Hazards?” that says: *Note: For this exercise, we are only considering biological hazards, even though the hazard analysis must also include analyses for physical and chemical hazards. Also note that the purpose of this exercise is to consider who is controlling the hazards and not, specifically, who is the foreign supplier. Under the FSVP rule, there is only one foreign supplier but there may be several entities that control the hazards. While an importer must only verify one foreign supplier, they must still consider all entities that control the identified hazards (scenarios are on the next slide).*
PPT, PM	Ch. 5	Slide 12 5-8	All	All	2	Changed title of slide 12 to ““Group Exercise: Who Is Controlling the Biological Hazards? (continued)” Changed the wording of the text beneath slide to say:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						Let's have a short group exercise. If you would like to take notes during the exercise, go to Chapter 5, page 15, in the Exercise Workbook.
PPT, PM	Ch. 5	Slide 13 5-9	All	All	1	Moved previous slide 12 "Evaluating Supplier Performance" and related text previously on page 5-8 to page 5-9.
PPT, PM	Ch. 5	Slide 14 5-9 & 5-10	All	All	2	Moved previous slide 13 "Food Safety Requirements that Apply to Your Supplier" to slide 14. Changed text on fourth row of table from "Canned pet foods" to "Canned foods" in the first column and from "LACF requirements, PC for Animal Food rule" to "LACF requirements" in the second column
PPT, PM	Ch. 5	Slide 15 5-10	All	All	1	Moved previous slide 14 "Researching Foreign Supplier's Compliance with U.S. Regulations" to slide 15.
PM	Ch. 5	5-10	KP			Changed KP to say: Currently, the food safety systems of New Zealand, Canada, and Australia have been recognized as having a comparable food safety system for certain foods under Systems Recognition.
PPT, PM	Ch. 5	Slide 16 5-11	All	All	1	Added new slide 16 "Researching Foreign Supplier's Compliance with U.S. Regulations" that includes screenshots of the FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals Web page and highlights some of the types of resources available. Added text beneath slide to say: There are many different resources available to the importer on FDA's "FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals" website available at:

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						https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm On the website, there is information about the final rule, related guidance, supporting material, additional information, and contact information. Under the "Additional Information" section on the right-hand side of the website, there is a link to "Supplier Evaluation Resources," which is a website providing links to the resources you will need in evaluating your foreign supplier. We will review this resource more fully in the next slide.
PPT, PM	Ch. 5	Slide 17 5-11 & 5-12	All	All	2	Moved previous slide 15 "Researching Foreign Supplier's Compliance with U.S. Regulations" and related text previously on page 5-10 to pages 5-11 & 5-12. Changed title of slide to "Researching Foreign Supplier's Compliance with U.S. Regulations (continued)" Changed the text beneath slide (top of page 5-12) to say: On the slide, you will see a screenshot of FDA's "Supplier Evaluation Resources" website. From this one page, you will be able to access multiple resources, such as import alerts, recalls, import refusals, and other important resources. The link to the "Supplier Evaluation Resources" website is: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm
PPT, PM	Ch. 5	Slide 18 5-12	All	All	1	Moved previous slide 16 "Additional Considerations" and related text previously on page 5-11 to page 5-12.
PPT, PM	Ch. 5	Slide 19 5-13	All	All	1	Moved previous slide 17 "Using a Qualified Individual and Documenting Your Evaluation" and related text previously on page 5-12 to page 5-13.

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PPT, PM	Ch. 5	Slide 20 5-13 & 5-14	All	All	2	Moved previous slide 18 “May I Use Another Entity’s Evaluation?” and related text previously on page 5-12 to pages 5-13 & 5-14.
PPT, PM	Ch. 5	Slide 21 5-14 & 5-15	All	All	1	Moved previous slide 19 “Approving Foreign Suppliers” and related text previously on page 5-13 to pages 5-14 & 5-15. Changed the last sentence of the text beneath slide to say: Remember, if your food presents no hazards requiring a control, the FSVP rule does not require you to perform an evaluation of your foreign supplier, nor do you have to approve your foreign supplier.
PPT, PM	Ch. 5	Slide 22 5-15	All	All	1	Moved previous slide 20 “Approving Foreign Suppliers” and related text previously on page 5-14 to page 5-15. Changed title of slide to “Approving Foreign Suppliers (continued).” Changed slide to say: **Your suppliers must be approved before food is imported!** • Therefore, you must carry out the hazard analysis and evaluations of your foreign supplier well in advance of importing food.
PPT, PM	Ch. 5	Slide 23 5-15 & 5-16	All	All	2	Moved previous slide 21 “Supplier Approval Summary” and related text previously on page 5-14 to pages 5-15 & 5-16. Changed second bullet in bottom rectangle to say: • Compliance with applicable U.S. food safety regulations (e.g., import alerts, warning letters)
PPT, PM	Ch. 5	Slide 24 5-16	All	All	1	Added new slide 24 “FSVP Foreign Supplier Evaluation Form Example” which includes a screenshot of new “Workaid E: FSVP Foreign Supplier Evaluation Form Example.”

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						Added text beneath slide that says: Note that there is a requirement to document the evaluation and approval process for your suppliers. The format on this slide is not mandatory under the rule, and may not fit every situation, but it serves as an example of a format that importers might use when performing a foreign supplier evaluation as part of the FSVP. The form could be modified as needed to fit many of the situations that you may face.
PPT, PM	Ch. 5	Slide 25 5-17	All	All	1	Moved previous slide 22 “Chapter 5: Summary” and related text previously on page 5-14 to page 5-17.
PPT, PM	Ch. 5	Slide 26 5-18	All	All	1	Moved previous slide 23 “Chapter 5: Questions” previously on page 5-16 to page 5-18.
CHAPTER 6 CHANGES						
PM	Ch. 6	6-1	PP 1	8 & 9		Changed the wording at the end of the second sentence to say: “…that your foreign supplier is doing what is necessary to ensure that food exported to the U.S. meets the same safety standards as food produce in the U.S.”
PPT, PM	Ch. 6	Slide 4 6-3 & 6-4	PP 1, 2, 3, & 5	All	1	Changed first bullet and sub-bullet on slide 4 to say: • You must establish written procedures to ensure: o The food you import is only obtained from suppliers you approved (based on evaluations of food and foreign supplier). PP 1: Changed the text to say: At this point, you have already performed a hazard analysis, considered who would be controlling the hazard needing to be controlled, and reviewed your foreign supplier’s performance (including the supplier's processes and procedures related to food safety, looked at the supplier’s food safety history, and compliance history with U.S. regulations). As a result of those activities, you may have already directed that your supplier

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						takes some corrective actions to address potential safety issues. If you have determined that the hazard requiring a control was a serious (SAHCODHA) hazard you may even have conducted an audit. All of this was done before you made the decision on whether to approve your foreign supplier. Hence, you may have already carried out activities to verify that the food you will be importing will be in accordance with U.S. food safety standards. PP 2: Bolded the paragraph that says: **You must also use your evaluation of the food and supplier to determine what verification activities are appropriate to ensure that the hazards needing controls in the food you import have been and will continue to be controlled.** PP 3: Bolded the last sentence that says: **FDA stated in the preamble to the FSVP rule that it intends to provide guidance on the temporary use of unapproved suppliers. You must document the use of your procedures.** PP 5: Changed the last paragraph to say: You should document your reason for using an unapproved supplier. Logically, FDA would not expect a "temporary" unapproved supplier to be to be utilized for a prolonged period of time.
PM	Ch. 6	6-4	KP			Added KP that says: FDA does not explain in the FSVP rule how to verify temporary suppliers, but it did state in the preamble that it intended to provide guidance. See narrative on this page regarding when an unapproved supplier might be used on a temporary basis.
PPT, PM	Ch. 6	Slide 5			1	Changed the slide 5 to say:

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		6-4				• Foreign supplier verification activities provide adequate assurances that the hazards requiring control in the food you import are: o Significantly minimized, or o Prevented. • You must determine which verification activities are appropriate, including their frequency, taking into account: o Who is controlling the hazard, and o Who is verifying that the hazards are controlled. • You must establish and follow written procedures for ensuring that verification activities are conducted.
PPT, PM	Ch. 6	Slide 6 6-5	PP 1 beneath slide	All	1	Bolded the text “must be established before” in the first bullet on slide 6. Changed the second sub-bullet under the second bullet to say: The risk posed by the food. Changed the first paragraph beneath slide to say: Remember that you already evaluated your foreign supplier and the risk posed by the food in order to approve the supplier in the first place (21 CFR 1.505). Now you are establishing written procedures to verify that appropriate foreign supplier verification activities are conducted for the foods you import. These activities should demonstrate that the hazards requiring a control have been significantly minimized or prevented. Bolded the last paragraph that says: **Knowledge of your foreign supplier’s procedures, processes and practices related to food safety can influence your decisions on which hazards require a control, as well as your choice of verification procedures. For example, if your foreign supplier produces only**

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						peanuts, there would not be a concern with controlling allergen cross-contact of non-peanut products with peanut allergens. However, a supplier that makes a variety of single and multi-variety nut products with different kinds of nuts may require verification activities to ensure that allergen cross-contact does not occur. Understanding how your foreign supplier controls allergens may be very important to your FSVP.
PPT, PM	Ch. 6	Slide 7 6-6	All	All	1	Moved previous slide 8 “Appropriate Verification Activities” and related text previously on page 6-7 to page 6-6. Unbolded the text “qualified individual” in the last bullet on slide.
PPT, PM	Ch. 6	Slide 8 6-7	All	All	1	Moved previous slide 7 “Verification Activities for Serious Hazards” and related text previously on page 6-6 to page 6-7. Changed the last sub-bullet on slide to say: An alternative, but equally effective, verification method can be chosen, but justify and document your rationale. Changed second sentence in the second paragraph to say: For example, in the case of a long-term supplier who has a good food safety track record, you may decide that annual audits are excessive and adjust the frequency to every 2 years instead, perhaps combined with some sampling and testing of the food.
PM	Ch. 6	6-7	KP			Moved KP previously on page 6-6 to page 6-7 and changed text to say: **SAHCODHA Hazards are those that would prompt a Class I* recall if they were to occur. The FSVP rule did not include a list of SAHCODHA hazards. However, because the Reportable Food Registry (RFR) requires reporting of**

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						these hazards, examples of SAHCODHA hazards may be found in the RFR (see Appendix 7 for RFR link). ***A Class I** recall situation is one in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death to humans or animals.
PPT, PM	Ch. 6	Slide 9 & 10 6-8	All	All	1 & 2	Changed slides 9 & 10, previously called “Illustrations” and “Illustrations (continued)” to “Group Exercise: What Could Be an Appropriate Verification Activity?” and “Group Exercise: What Could Be an Appropriate Verification Activity? (continued).” Changed slide 9 to say: **Scenario 1:** If your supplier is providing food from a region where high levels of heavy metals (e.g., lead or cadmium) have been found in similar foods, what could be an appropriate activity to verify that heavy metal levels are within U.S. limits (if any) or at normal background levels? **Answer:** Periodic sampling and testing by the supplier or a reputable laboratory could be an appropriate verification activity. Changed text beneath slide 9 to say: So, let’s work through a short group exercise. Raise your hand to answer the question. Discuss what could be an appropriate verification activity for the scenarios described in the scenario. After a brief discussion, the instructor will display the answer. Note: If desired, you can write down the answer to Scenario 1 (above) in the Exercise Workbook (see Chapter 6, page 16). Changed slide 10 to say: **Scenario 2:** If your evaluation of the manufacturer, who is your foreign supplier, reveals that temperature controls for a processing step are critical for controlling pathogens, what

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						could be an appropriate activity to verify that temperature controls for the processing step were appropriately maintained? **Answer:** The review of the supplier's records of temperature recordings could be an appropriate verification activity. Changed text beneath slide 10 to say: To write down the answer to Question 2, refer to Chapter 6 in the Exercise Workbook.
PM	Ch. 6	6-8	KP			Changed KP to say: An example of testing as a verification activity: Pesticides may be a "known or reasonably foreseeable" hazard if FDA (or you) have found in the past high residue levels of pesticides not approved in the U.S. for use in the particular commodity. While sampling and testing may be an appropriate verification activity in that case, an alternative verification activity could be requesting records of pesticide used (e.g., pesticide name, application rates, application dates, preharvest interval) for the food in question.
PM	Ch. 6	6-9	KP Top of page			Changed KP to say: Audits to private standards/schemes may contribute to the safety of the food supply but may not meet the requirements of the FSVP rule. Under this rule, audits must consider the hazards requiring a control and all applicable FDA food safety standards, including the hazards you identified in your hazard analysis. Also, audits must be conducted by a qualified auditor, as defined in FSVP rule (sec. 1.500).
PM	Ch. 6	6-9	KP Bottom of page			Changed KP to say: FDA expressed the following in the preamble to the FSVP rule: "We believe that as importers and foreign suppliers become more familiar with the FSVP requirements, more suppliers are likely to arrange to be audited and share the audit results with

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						multiple U.S. importers." This could be done "by a foreign government employee with appropriate technical expertise obtained through education, training, and/or experience, as long as the foreign official considers applicable FDA food safety standards."
PM	Ch. 6	6-9 & 6-10	All	All		Bolded the last sentence in the first paragraph that says: **Nevertheless, whenever an audit is conducted, it must be conducted by a qualified auditor, who can understand the hazards identified in your hazard analysis, the effectiveness of controls for those hazards, and the relevant FDA regulations.** Changed the second paragraph to say: The definition of a qualified auditor is included in the FSVP rule, and in the Definitions and Acronyms in Appendix 10. Note that a qualified auditor can be a government employee or a private entity. If FDA officially recognizes that another country's food safety system is comparable for certain foods under Systems Recognition, and if your foreign supplier is providing food that is within the scope of that official recognition and under the jurisdiction of the government authority responsible for that food safety system, the auditor may inspect to that country's applicable standards. Combined the third (bottom of page 6-9) and fourth paragraph (top of page 6-10) and changed the text to say: It is important to ensure that audits include both a records review and the observation of supplier practices for a complete picture. Comprehensive systems audits that include records reviews are more likely to reflect conditions throughout the year, as opposed to an audit that examines the state of the facility at a particular time. The audit must consider applicable FDA food safety regulations, including the CGMP and Preventive Controls (process, allergen, sanitation, and supply-chain) (for suppliers subject to those

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						requirements), compliance with the Produce Safety rule (for farms subject to that rule), and any other applicable FDA food safety regulation (e.g., LACF). In all cases, the audit must address the specific hazards identified in your hazard analysis. In theory, an importer's hazard analysis may not be identical to a supplier's hazard analysis, if one exists, but they should identify the same hazards and if not, they will need to be reconciled. It also must include a review of the supplier's written food safety plan, if any, and its implementation (21 CFR 1.506(e)(1)(i)). Other regulations that an auditor might consider in auditing a foreign supplier producing food for sale in the U.S. are the FSMA rules pertaining to "Sanitary Transportation of Human and Animal Food" and food defense ("Mitigation Strategies to Protect Food Against Intentional Adulteration").
PM	Ch. 6	6-10	KP			Deleted KP from page 6-10.
PPT, PM	Ch. 6	12 6-10 & 6-11	PP 2	5-8	1	Changed the second bullet to say: • Documentation must demonstrate that your supplier is using processes and procedures that control the hazards requiring a control. Changed the second sub-bullet under the third bullet to say: • Qualification of the auditor, Changed last paragraph to say: It should be noted that the FSVP rule also accepts food safety inspections, as substitutes for onsite audits, from appropriate officials of a foreign government, but only if FDA has recognized the food safety system of the country as comparable for certain foods under Systems Recognition, and provided that the food that is the subject of the onsite audit is within the scope of that official recognition, and that the foreign supplier is under the regulatory oversight of the that country.

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PPT, PM	Ch. 6	Slide 13 6-11 & 6-12	PP 3	4	1	Unbolded the text "qualified individual" in the last sub-bullet under the second bullet on slide 13. Changed list item 2, in paragraph 4 (top of page 6-12) to say: 2. The tests conducted (including the analytical methods used) and the dates, and
PPT, PM	Ch. 6	Slide 14 6-12			1	Unbolded the text "qualified individual" in the last bullet on slide 14.
PPT, PM	Ch. 6	6-15	PP 2	1 & 2		Bolded first sentence in second paragraph that says: **There may be several entities, in some cases, engaged in such controls.**
PM	Ch. 6	6-15	KP			Added KP that says: FDA's Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA This guidance is intended for any entity that is subject to certain provisions (in part 117, part 507, the produce safety regulation, or the FSVP regulation) that require a disclosure statement, in documents accompanying food, that certain hazards have not been controlled by that entity. This guidance is not intended to address other requirements of part 117, part 507, the produce safety regulation, or the FSVP regulation. The guidance is available at: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm524553.htm
PPT, PM	Ch. 6	Slide 19 6-16 & 6-17	PP 2 beneath slide	3-5	1	Added an asterisk after "written assurance" in the last sub-sub-bullet on slide 19 and added a footnote at the bottom of the slide that says: *FDA has granted a two-year extension (until May 2019 at the earliest) for the written assurance requirement.

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						Changed last paragraph of text beneath slide (bottom of page 6-16 & top of 6-17) to say: And so, it goes down the line if it is your customer's, customer's, customer, etc., who controls the hazard. But note that FDA has granted a two-year extension (until May 2019 at the earliest) for the written assurance requirement while it considers concerns raised by industry.
PM	Ch. 6	6-16	KP			Combined the KP and IN that was on page 6-17 to a KP on page 6-16 that says: While the requirement to obtain written assurances is in the final rule, the compliance date for this provision has been extended for two additional years past the original compliance dates. The earliest compliance date for the written assurance provision is May 28, 2019. This extension was granted in response to industry's concerns over the burden of obtaining the assurances in complex supply chains (80 FR (Aug. 24, 2016)). This extension did not pertain to the disclosure requirement. https://www.fda.gov/food/guidanceregulation/fsma/ucm517545.htm
PPT, PM	Ch. 6	Slides 20 & 21 6-17 & 6-18			1 & 2	Slide 20: Added an asterisk after the text "Written Assurances" in the title of the slide "Written Assurances* Must Include" Added a footnote at the bottom of the slide that says: *FDA has granted a two-year extension (until May 2019 at the earliest) for the written assurance requirement. Slide 21: Added an asterisk after the text "Written Assurances" in the title of the slide "Actions Must Be Consistent with Written Assurances*" Added a footnote at the bottom of the slide that says:

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						*FDA has granted a two-year extension (until May 2019 at the earliest) for the written assurance requirement. Changed text beneath slide 21 (bottom of page 6-17 & top of page 6-18) to say: When and if they go into effect, the customer or other entity in the distribution chain that provides a written assurance must act consistently with the assurance and document the actions it takes to satisfy the written assurance.
PPT, PM	Ch. 6	Slide 22 6-18			1	Changed the title of slide 22 to say: Alternative System to Demonstrate that Hazards Controlled After Importation Changed sub-bullet 1 to say: • Have established and implemented a system (other than disclosures and assurances) that ensures control of a hazard(s) in the food at a subsequent distribution step, and
PPT, PM	Ch. 6	Slide 23 6-19	PP 1	6	1	Unbolded the text “qualified individual” in the first sub-bullet. Unbolded the text “qualified individual” and changed the wording of the second sub-bullet to say: Your qualified individual under the FSVP rule must assess the appropriateness of the verification activities and must document your review and assessment, and document that the original determination was performed by a qualified individual. Changed the bolded last sentence in paragraph 1 to say: **You need to remember, however, that the FSVP importer in the U.S., is ultimately responsible for appropriate verification activities.**

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PPT, PM	Ch. 6	Slide 24 6-20	All	All	1	Changed the title of slide 24 to "Group Discussion: What Supplier Verification Activity(ies) Would Be Appropriate in the Following Scenario?" Removed the previous scenario 1 and related image and added the two questions to be asked for the group discussion. The slide now says: Scenario: Importing fresh sliced tomatoes. • **Question 1:** What hazard(s) require a control? • **Question 2:** What verification activity(ies) would be appropriate? Changed the text beneath slide to say: Instructions: The instructor will lead participants in a group discussion with the intent to first identify what hazard(s) require a control and then what verification activity(ies) would be appropriate. If you would like to take notes during the discussion, refer to Chapter 6, page 16, in the Exercise Workbook.
PPT, PM	Ch. 6	Slide 25 IG=6-20 PM=6-20 & 6-21	PP 4	All	IG=1 PM=2	Unbolded the text "qualified individual" in bullets 1, 2, & 3. Changed bullet 3 to say: • Your foreign supplier should neither determine what the appropriate verification activities should be, nor perform the activities, except that they may test product or provide records (but not conduct the record review). Bolded the last paragraph of text beneath slide that says: **Note that whenever performing an on-site audit is chosen as an appropriate verification activity, it must be performed by a qualified auditor as defined by FDA. Qualified auditors are qualified individuals that have technical expertise obtained through education, training,**

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						or experience (or a combination thereof) necessary to perform the auditing function.
PPT, PM	Ch. 6	Slide 26 IG=6-22 PM=6-21	ALL	3	1	Unbolded the text “qualified individual” in bullet 1 on slide 26. Bolded the first sentence in the paragraph beneath text that says: The qualified individuals who conduct foreign supplier verification activities must not have financial conflicts of interests that could influence the results of verification activities (21 CFR 1.506(e)(4)).
PM	Ch. 6	IG=6-22 & 6-23 PM=6-22	PP 2	2		Changed the second sentence in the second paragraph to say: In some cases, you may also decide that you need to replace that foreign supplier with another supplier.
PM	Ch. 6	6-22	RN			Added RN that says: Corrective actions will be covered in more detail in Chapter 7.
PPT, PM	Ch. 6	Slide 28 6-23	All	All	1	Added new slide 28 “Verification Activities—Before and After Importing” Added new text beneath slide that says: Sec. 1.506(e)) requires that importers conduct a verification activity before importing food, as well as periodically thereafter. Although the initial verification conducted prior to importation is not linked in the rule to supplier approval, or as a condition for foreign supplier approval, it may be that the first verification could be conducted and be part of the hazard and/or supplier evaluations.
PPT, PM	Ch. 6	Slide 29 IG=6-24 PM=6=23 & 6-24	All	All	IG=1 PM=2	Added new slide 29 “FSVP Foreign Supplier Verification Activity(ies) Worksheet Example” which includes a screenshot of new “Workaid F: FSVP Foreign Supplier Verification Activity(ies) Worksheet Example.”

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						Added new text beneath slide that says: The FSVP Foreign Supplier Verification Activity(ies) worksheet example on the slide, relates to the supplier verification process for food that is imported and governed by the FSVP rule. The format is not mandatory under the rule, but it is an example of a format that importers might use when performing foreign supplier verification as part of the FSVP. The form could be modified as needed to fit many of the situations that you may face.
PPT, PM	Ch. 6	Slide 30 IG=6-25 PM=6-24	All	All	1	Moved previous slide 28 “Chapter 6: Summary” and related text previously on page 6-23 to page IG=6-25 and PM=6-24. Added a new sub-bullet 2 to say: • Determination of appropriate verification activities must be based on the evaluation of a foreign supplier’s performance and the risk of the food. Moved original sub-bullet 3 to become sub-bullet 2. Moved original sub-bullet 2 to become sub-bullet 4 and changed it to say: • SAHCODHA hazards require either annual onsite auditing or other activities providing adequate assurance. Moved original sub-bullet 4 to become sub-bullet 5. Added new sub-bullet 6 that says: • Documentation is key. Changed the text beneath slide to say: This chapter has discussed: • The need for written procedures for: o Ensuring that you only obtain food from approved suppliers, and

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						o Conducting verification activities. • Determination of appropriate verification activities must be based on the evaluation of a foreign supplier's performance and the risk of the food • Verification activities must be appropriate for the food, the hazard, and who controls the hazard. • SAHCODHA hazards require either annual onsite auditing or other activities providing adequate assurance. • The choice and performance of verification activities must be accomplished by qualified individuals under the FSVP rule. • Documentation is key.
PPT, PM	Ch. 6	Slide 31 IG=6-26 PM=5-25	All	All	1	Moved previous slide 29 "Chapter 6: Questions" and related text previously on page 6-24 to page IG=6-26 and PM=6-25.
CHAPTER 7 CHANGES						
PPT, PM						Changed chapter title "Chapter 7: Reevaluation of Foreign Supplier" to "Chapter 7: Reevaluation of Foreign Supplier Performance and Food Risk, and Corrective Actions"
PPT, PM	Ch. 7	Slide 3 7-2 & 7-3	All	5 & 6	1	Changed Objective 4 to say: 4. Determine appropriate corrective actions to ensure compliance. Added new Objective 5 that says: 5. Determine appropriate corrective actions to address deficiencies in your FSVP. Moved original Objective 5 to become Objective 6. Changed list item 4 to say: Determine appropriate corrective actions to ensure

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						compliance, Added new list item 5 that says: Determine appropriate corrective actions to address deficiencies in your FSVP, and Moved original list item 5 to become list item 6.
PPT, PM	Ch. 7	Slide 4 7-3	All	All	1	Changed slide 4, bullets 1 & 2 to say: • At least every 3 years you must reevaluate the previously identified factors relating to the evaluations of your foreign suppliers and the foods you import and take appropriate actions, if necessary. • At any time, you become aware of new information that may affect your food and foreign supplier performance evaluations, you must promptly review the appropriateness of your FSVP. Changed the text beneath slide to say: At a minimum, your food risk and foreign supplier performance must be evaluated every 3 years. In performing your evaluations, you must reevaluate the previously identified factors relating to your foreign suppliers and the foods you import, and take appropriate corrective actions on the basis of the reevaluation, if necessary (21 CFR 1.505(c)). FSVP importers must promptly review their evaluations pertaining to the food and their foreign supplier's performance at any time you become aware of new information that may affect your prior evaluations.
PPT, PM	Ch. 7	Slide 6 7-4 & 7-5	All	All	2	Changed slide 6 to say: • If you are a "very small importer," operating under modified FSVP requirements that allow you to rely on written assurances from your supplier: o A supplier evaluation and reevaluation are not required.

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						• However, if you are an importer that imports foods from "certain small foreign suppliers" (sec. 1.512(a)(2)), or an importer who imports dietary supplements (sec. 1.511(c)), you must: o Conduct a supplier reevaluation as required under the applicable sections. • You must also monitor whether the modified requirements continue to apply. Changed text beneath slide to say: If you are operating under certain modified FSVP requirements that allow you to rely on written assurances from your foreign supplier because you are a very small importer under section 1.512(a)(1)), a supplier evaluation and reevaluation are not required. However, if you are an importer that imports certain foods from certain small foreign suppliers under section 1.512(a)(2) or an importer of certain dietary supplements under section 1.511(c), you must conduct supplier reevaluation as required under the applicable sections. You must also monitor whether the modified requirements continue to apply.
PPT, PM	Ch. 7					Deleted previous slide 7 "FSVP Reevaluations When Relying Upon Entities Other than Your Foreign Supplier to Control Hazards" and related text.
PPT, PM	Ch. 7	Slide 7 7-5	All	All	1	Moved previous slide 8 "What Issues Could Trigger a Reevaluation and Why?" and related text previously on page 7-6 to page 7-5 and changed the slide title to "Group Discussion: What Issues Could Trigger a Reevaluation and Why?" Changed the text beneath slide to say: Let's have a short group discussion. If you would like to take notes, go to Chapter 7, page 17, in the Exercise Workbook.

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PPT, PM	Ch. 7	Slide 8 7-6	All	All	1	Moved previous slide 9 “Considerations for Reevaluation” and related text to page 7-6.
PPT, PM	Ch. 7	Slides 9 & 10 7-7	All	All	1	Added new slide 9 “FSVP Foreign Supplier Reevaluation Form Example” which includes a screenshot of page 1 of the new “Workaid G: FSVP Foreign Supplier Reevaluation Form Example” Added new slide 10 “FSVP Foreign Supplier Reevaluation Form Example (continued)” which includes a screenshot of page 2 of the new “Workaid G: FSVP Foreign Supplier Reevaluation Form Example” Slide 9: Added text beneath that says: This slide shows page 1 of a type of form that may be used to document your supplier reevaluation for food that is imported and governed by the FSVP rule. The format is not mandatory under the rule, but it is an example of a format that importers might use when performing a foreign supplier reevaluation as part of the FSVP. The form could be modified as needed to fit many of the situations that you may face. Slide 10: Added text beneath that says: This slide shows page 2 of a type of form that may be used to document your supplier reevaluation for food that is imported and governed by the FSVP rule.
PPT, PM	Ch. 7	Slide 11 7-8	All	All	1	Moved previous slide 10 “Relying on Another Entity’s Reevaluation” and related text previously on page 7-7 to page 7-8. Unbolded the text “qualified individual” in sub-bullets 1 & 1 under bullet 2.

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PPT, PM	Ch. 7	Slide 12 7-9	All	All	1	Moved previous slide 11 “What Are Corrective Actions?” and related text previously on page 7-8 to page 7-9 and changed the title to “Corrective Actions to Ensure Compliance.” Changed slide 12 to say: • Corrective actions are the steps necessary to ensure that future shipments of that food are in compliance with U.S. food safety requirements. • If you find through a routine reevaluation, verification activities, or other means that your foreign food supplier is NOT producing food that meets applicable U.S. safety standards, you will need to take corrective action. o Your qualified individual must determine whether corrective actions are necessary. o Corrective actions must be taken promptly once you ascertain that a food safety problem exists and that corrective actions are necessary. o You must verify that appropriate corrective action has been taken. o You must also document your investigations, corrective actions, and changes to your FSVP (1.508(b)). Changed paragraph 2, 3, & 4 to say: PP 2: Your job as the FSVP importer, however, is to develop and carry out foreign supplier approval and other verifications to ensure that your suppliers are producing the food you import in compliance with processes and procedures that provide the same level of public health protection as the preventive controls requirements and the produce safety rule, if applicable, and that the food is neither adulterated under

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						section 402 of the FD&C Act nor misbranded with respect to the labeling of major food allergens. PP 3: You may discover that your foreign supplier's food safety processes and procedures have failed to produce food for export to the U.S. that complies with applicable U.S. food safety requirements. You may learn of this noncompliance through your reevaluation, the results of your verification activities, or through some other means, such as consumer complaints. Once you discover the noncompliance, corrective actions must be taken to protect public health and prevent a reoccurrence. Your qualified individual must be the person to determine whether corrective actions are necessary to ensure compliance. PP 4: If corrective actions are needed to ensure compliance, then you, as the importer, must verify that appropriate corrective actions are taken and, as discussed below, you must document them appropriately. Moved PP 5 to paragraph 1 of the text beneath slide 13 on page 7-10.
PPT, PM	Ch. 7	Slide 13 7-10	All	All	1	Moved previous slide 12 "Appropriate Corrective Actions" and related text previously on page 7-9 to page 7-10. Moved previous PP 5 from beneath slide 12, page 7-9 to paragraph 1 of the text beneath slide 13 on page 7-10. Changed PP 1 on page 7-10 to say: When you learn of system failures or actual food safety issues from your foreign suppliers, through consumer/customer complaints, your verification procedures, or otherwise, you need to consider what corrective actions are appropriate for

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						you to take. You will need to determine if unsafe product was actually produced, or if your foreign supplier took appropriate corrective actions to prevent any contaminated food from being produced or being exported. The action you take should be appropriate to the nature of the hazard, the situation, and your and your supplier's ability to prevent a recurrence of the problem. Nevertheless, some situations require substantial corrective action, including discontinuing use of the foreign supplier. You must be confident that the consuming public is not exposed to any food that could cause illness or injury.
PPT, PM	Ch. 7	Slide 14 7-11	All	All	1	Added new slide 14 "Corrective Actions to Address Deficiencies in Your FSVP." Added new text beneath slide that says: While taking action to address your supplier's noncompliance is critical, you must also assess whether you need to take corrective action to address deficiencies in your own FSVP. This is most likely when you discover your supplier's deficiencies through means outside your FSVP, such as through consumer complaints. You need to ask yourself, "Why you didn't find the deficiencies yourself"? The rule requires that you investigate the matter and, if you discover deficiencies in your FSVP, make changes to address them.
PPT, PM	Ch. 7	Slide 15 7-11 & 7-12	All	All	2	Moved previous slide 13 "Documenting Corrective Actions" previously on page 7-10 to page 7-11. Changed text on slide to say: • You must document any corrective actions you take, including: o All corrective actions involving the supplier/food, and o Any investigations and changes made to your FSVP.

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						Changed text beneath slide (top of page 7-12) to say: Finally, you must document all corrective actions taken (1.508(a)). If you discover the noncompliance through means other than your reevaluation or your verification activities, you must also document your investigations and changes to your FSVP (1.508(b)), in addition to your corrective actions.
PPT, PM	Ch. 7	Slide 16 7-12	All	All	1	Moved previous slide 14 “Chapter 7: Summary” and related text previously on page 7-11 to page 7-12. Changed sub-bullet 3 to say: • The need to take appropriate and effective corrective actions to address supplier/food noncompliance. Added new sub-bullet 4 that says: • The need to investigate and take corrective actions to address deficiencies in your FSVP. Moved previous sub-bullet 4 to become sub-bullet 5. Changed text beneath slide to say: This chapter has covered the following: • When you must reevaluate your FSVP. • What to consider when you conduct your reevaluation. • The need to take appropriate and effective corrective actions to address supplier/food noncompliance. • The need to investigate and take corrective actions to address deficiencies in your FSVP. • The need to document reevaluations and corrective actions.
PPT, PM	Ch. 7	Slide 17 7-13	All	All	1	Moved previous slide 15 “Chapter 7: Questions” previously on page 7-12 to page 7-13.
CHAPTER 8 CHANGES						

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PPT, PM	Ch. 8					Changed chapter title “Chapter 8: Importer Identification” to “Chapter 8: Importer Identification at Entry”
PM	Ch. 8	8-1	All	All	1	Changed text beneath slide to say: Under the FSVP rule, you must provide additional data to U.S. Customs when a food is offered for entry into the United States.
PM	Ch. 8	8-2	All	All		Moved paragraph 1 to become paragraph 1 under slide 4. Changed previous paragraph 2, now paragraph 1, to say: This chapter will discuss the requirement, what information must be submitted, and how to obtain a DUNS number. It will discuss the need to ensure that the responsible FSVP importer is correctly identified by the entry filer and that, if the FSVP importer is the U.S. agents or representatives of the foreign supplier, written consent is required to be identified in an entry filing. This chapter also makes the linkage between FDA oversight/enforcement and the FSVP importer’s identification information into the U.S. Customs entry system.
PM	Ch. 8	8-2	KP			Added KP that says: Other than providing these new data elements regarding the FSVP importer at entry, the admissibility process will not change under the FSVP rule.
PPT, PM	Ch. 8	Slide 4 8-2 & 8-3	All	All	2	Moved slide 4 “U.S. Entry Procedures” and related text previously on page 8-3 to pages 8-2 & 8-3. Changed slide 4 to say: • The FSVP rule will not generally affect FDA's current entry process. • The only change you will see at entry is the requirement to identify the FSVP importer at entry. • Changes have been implemented to the Customs and Border Protection (CBP) entry system to accept this data.

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						Moved previous paragraph 2 beneath slide 3 to become paragraph 1 beneath slide 4 that says: In general, you will not see changes to the entry procedures as a result of the FSVP rule. The one exception is that you must identify the FSVP importer at the time of entry. Identifying the FSVP importer at time of entry should be a simple task. Still, there are a number of aspects of this FSVP process that can be delineated and certain aspects that must be stressed to ensure it is done properly. Changed previous paragraphs 1 and 2, now 2 and 3, to say: FSVP requires that the FSVP importer identification requirements be entered through the Customs entry system for each applicable line entry. The Customs entry system has been modified to accept this additional data. It is important to understand that FDA will not assess FSVP compliance on a shipment by shipment basis during the admissibility process. Rather, FDA will assess the FSVP importer's compliance by reviewing FSVP records at the FSVP importer's place of business in the U.S., as identified through the new data requirements.
PPT, PM	Ch. 8	Slide 5 8-3	All	All	1	Moved previous slide 6 "Importance of Identifying FSVP Importer" and related text previously on page 8-5 to page 8-3. Changed text beneath slide to say: Once your compliance date has arrived for a particular line entry, you must provide the additional information properly identifying the FSVP importer when the entry is offered for import. If you do not, your filer will receive an error message from Customs. The information entered will allow FDA to build an inventory of FSVP importers for oversight purposes. You should be working with your filer prior to entry to ensure he/she has the appropriate information to be submitted to Customs.

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						Moved previous slide 5 “When Importing Food, What FSVP Information Must Be Provided at Entry?” and related text previously on page 8-5 to pages 8-4 and 8-5. Changed the title of slide to “What FSVP Information Must Be Provided at Entry?” Changed slide to say: • For each line entry of food product presented for entry into the U.S., FSVP requires the following information to be provided electronically to identify the FSVP importer of the food: o Name o Electronic mail address o Unique facility identifier (UFI) (more detail to follow)
PPT, PM	Ch. 8	Slide 6 8-4 & 8-5	All	All	1	Changed text beneath slide to say: The entity role code, FSV, mentioned earlier, is required to be input into the system for each line entry of food product offered for importation into the U.S. (21 CFR 1.509(a)). The FSV entity role code will trigger a request for additional information that will identify the FSVP importer: • Firm Name • Email address • Unique Facility Identifier If the line entry is exempt from the requirements of FSVP or the product being submitted for entry is not subject to the rule based on the compliance date applicability, the AofC codes FSX (FSVP Exempt or compliance date applicability) or RNE (Research and Evaluation) are to be used. If line item is a food and one of these two codes are not transmitted as stated above, the entry will be rejected by the CBP’s ACE system. The rejection will generate an error

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						message, so the filer can make the appropriate adjustments to the entry submission and retransmit the entry line. FDA will be able to view transmitted data to ensure the accuracy of the information and determination if the correct coding was used at the time of submission. For additional technical information some may want to reference FDA's Supplemental Guidance for the CBP and Trade Automated Interface Requirements at: https://www.cbp.gov/sites/default/files/assets/documents/2017-Jan/FDA%20Supplemental%20Guide%20Release%202.5%20FINAL%20DEC%2028%202016%20.pdf
PPT, PM	Ch. 8	Slide 7 8-5	All	All	1	Moved slide 7 "You Must Have a Unique Facility Identifier" and related text previously on page 8-6 to page 8-5. Changed slide to say: • The FSVP rule requires that each FSVP importer have a unique facility identifier (UFI) that is acceptable to FDA to be placed in the Customs entry filing. • FDA has recognized the DUNS number as acceptable. • The FSVP importer must, therefore, obtain a DUNS number prior to your first compliance date. o Anyone can obtain at no cost from Dun & Bradstreet o The DUNS number provided must be associated with the person listed as the FSVP importer Changed text beneath slide to say: The final FSVP rule requires the submission at entry of a unique facility identifier (UFI). In a guidance issued in March 2017, FDA recognized the DUNS number as acceptable. At

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						this time, the DUNS number is the only UFI recognized by FDA. DUNS numbers can be obtained online by anyone and at no cost from: http://www.dnb.com/government/duns-request.html It should be mentioned that DUNS numbers are specific to physical locations; therefore, an importer with more than one physical location likely would have more than one DUNS number. Make sure the DUNS number provided is associated with the person/company location identified as the FSVP importer because this is the location FDA will inspect (typically the location at which FSVP records are maintained, although records may be kept offsite under the rule).
PM	Ch. 8	8-5	KP			Added KP that says: If you already have a DUNS number: You do not need to get a new one. If you do NOT have a DUNS number, you should get one prior to your first compliance date. If you are unable to obtain a DUNS number, FDA will allow filers to transmit the value "UNK" (to represent "unknown") in the UFI field. FDA will contact FSVP importers for whom "UNK" was transmitted to ensure that they understand the UFI FSVP regulation requirement and take steps to obtain a UFI.
PM	Ch. 8	8-6	KP			Added KP that says: Basically, all commercial CBP entries are now filed electronically via special software (offered by private vendors) that interfaces with CBP's ACE system. The ACE system is the primary system through which the trade community reports imports and exports and the government determines admissibility. ACE is already required for most entries. CBP ACE Home page: https://www.cbp.gov/trade/automated

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PM	Ch. 8	8-6	KP			Added KP that says: FDA Guidance on Complying with the UFI Requirement at Entry: • Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation: https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM549647.pdf • Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm
PPT, PM	Ch. 8	Slide 8 8-6	All	All	1	Deleted previous slide 8 “Obtaining a Free DUNS Number” Changed previous slide 9 “Obtaining a Free DUNS Number (continued)” title to “Request a Free DUNS Number,” added a sub-title “To request a FREE DUNS number go to Dun & Bradstreet’s Website http://www.dnb.com/government/duns-request.html,” and replaced previous screenshot with new screenshot from the above link. Combined text beneath previous slides 8 & 9 and moved new slide 8 and combined text to page 8-6.
PPT, PM	Ch. 8	Slide 9 8-6 & 8-7	All	All	2	Added new slide 9 “Complying with the Unique Facility Identifier (UFI) Requirement at Entry” that says: • When a food product under FDA oversight is offered for entry into the U.S., the CBP Automated Commercial Environment (ACE) system will prompt the filer to transmit one of the following codes:

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						o An entity role code "FSV" – signals to ACE system that entry line subject to FSVP rule; ▪ ACE will request FSVP importer's name, email address, and DUNS number o An Affirmation of Compliance code "FSX" – entry line is exempt from or not yet subject to FSVP; o An Affirmation of Compliance code "RNE" – entry line is exempt from FSVP as food is being imported for research or evaluation. • If one of these codes is not transmitted, the filer will receive an error message. • The filer can make the appropriate adjustments to the entry submission and retransmit the entry line. Added text beneath slide (bottom of 8-6 & top of 8-7) that says: As of May 30, 2017, the data elements that relate to the FSVP rule are utilized and accepted by CBP. The electronic filing is done by a licensed custom broker. As the entry information is input into CBP's Automated Commercial Environment (ACE) the system will be able to detect based on an agency program code FOO if the line entry is associated with a food (human or animal) commodity. Once this detection has been made the system will prompt the filer to enter one of two types of codes: An entity role code FSV, which will signal to the system that the line entry is under the jurisdiction of the FSVP regulation or; an Affirmations of Compliance (AofC) using either of the AofC codes FSX for "FSVP Exempt" or RNE for "Research and Evaluation."
PPT, PM	Ch. 8	Slide 10 8-7	All	All	1	Added new slide 10 "Example of a Software Screen Where You Select Role Code FSV and Enter FSVP Importer Information" which includes a screenshot of the SmartBorder

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						software screen for FSVP role code and FSVP importer information. Added text beneath slide that says: The software used to provide this information is purchased by the filer from a software company, not FDA, and will vary. The screenshot on the slide is one example of a software screen where the role code FSV is to be selected and the FSVP importer information is to be entered. **Note: There are many different software vendors and the screens may be different for each one, but the required information will be the same no matter what software the licensed broker is using.** At the top of the screenshot, you can see where the FSV code for FSVP is available to select. This is the role code we mentioned earlier. When the FSV code is selected, this software requires, among other things, the entry of the UFI (DUNS #) and the name and an email address. The filer's software may also request additional information, such as the physical address. If so prompted, the address entered should be that of the FSVP importer.
PPT, PM	Ch. 8	Slide 11 8-8	All	All	1	Added new slide 11 “Example of a Software Screen When Entering Affirmation of Compliance (AofC) Code” which includes a screenshot of SmartBorder software that shows examples of where to enter the AofC code. Added text beneath slide that says: The screenshot in the slide above is showing the two AofC codes (FSX and RNE) mentioned earlier. Again, if the line entry is exempt from the requirements of FSVP or the product being submitted for entry is not subject to the rule based on the compliance date applicability, the AofC codes FSX (FSVP Exempt or compliance date applicability) or RNE (Research and Evaluation) are to be used.

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PPT, PM	Ch. 8	Slide 12 8-8	PP 1 & PP 2	3 (1) & 1, 4 (2)	2	Changed previous slide 10 “Some Importer Identification Issues” to slide 12 and changed bullets 1 and 2 to say: • FDA will hold the FSVP importer identified on the CBP filing responsible for meeting the FSVP requirements and will inspect that entity for compliance. • Be sure the person filling out the CBP entry filing for any food you import or any imported food you receive knows the proper party to enter as the FSVP importer. Changed the first sentence in paragraph 1 to say: Several points should be made relative to the FSVP importer named on the CBP entry filing. First, FDA will conduct oversight, that is, inspect the FSVP importer, based on an inventory, which will be established through this identification requirement of the regulation. Changed the first sentence in paragraph 2 to say: Second, it is important that you ensure that the person filling out the CBP entry filing for any food you import or any imported food you receive knows the proper party to enter as the FSVP importer, as well as the electronic mail address and DUNS number.
PPT, PM	Ch. 8	Slide 13 8-9 & 8-10	PP 1 & PP 2	1-4 & 7-9	1	Changed previous slide 11 “Some Importer Identification Issues (continued)” to slide 13. Related text is now on pages 8-9 & 8-10. Changed the first and second sentences in paragraph 1 to say: Remember that when there is no U.S. "owner or consignee," U.S. agents and representatives of foreign owners and consignees can serve as the FSVP importer. In that case, the U.S. agent or consignee is required to consent to be the FSVP importer in writing. Changed the third sentence in paragraph 2 to say:

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						If you are concerned, you may want to periodically check FDA's public list of FSVP importers to see if you are named.
PPT, PM	Ch. 8	Slide 14 8-10	All	All	1	Changed previous slide 12 “Group Exercise: Importer Designation at Entry—Scenario 1” to slide 14. Changed the first bullet to a bolded sub-header with remaining bullets 2-6 becoming bullets 1-5 beneath it. Changed bullet 3 to say: • The distributor handles all shipping arrangements and CBP entry filing. Added a second bolded sub-header beneath bullet 5 and added the two questions at the bottom of the slide that say: **Questions:** 1. How is a decision made on who should be the FSVP importer designated on the CBP entry filing? 2. Who is in the best position to be the FSVP importer? Changed text beneath slide to say: Review Scenario 1 and participate in a group discussion to answer the questions below. If you would like to take notes during the discussion, go to Chapter 8, page 18, in the Exercise Workbook. 1. How is a decision made on who should be the FSVP importer designated on the CBP entry filing? 2. Who is in the best position to be the FSVP importer?
PPT, PM	Ch. 8	Slide 15 8-11	All	All	1	Moved previous slide 13 “Group Exercise: Importer Designation at Entry—Scenario 2” and related text previously on page 8-10 to page 8-11. Changed the first bullet to a bolded sub-header with remaining bullets 2-3 becoming bullets 1-2 beneath it.

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						Added a second bolded sub-header beneath bullet 2 and added the question at the bottom of the slide that says: 1. What options are available for avoiding this scenario? Changed the text beneath slide to say: Review Scenario 2 and participate in a group discussion to answer the question below. Again, if you would like to take notes during the discussion, go to Chapter 8, page 18, in the Exercise Workbook. 1. What options are available for avoiding this scenario?
PPT, PM	Ch. 8	Slide 16 8-11 & 8-12	All	All	2	Changed previous slide 14 “Chapter 8: Summary” to slide 16. Changed slide 16 to say: • In this chapter, we have discussed: o It is important to identify the FSVP importer at entry. o The traditional CBP entry process is the same except that now you must also identify the FSVP importer by providing additional data elements to CBP upon entry. o You must know what information is required, how to obtain a DUNS number, and how to enter the required information at entry. o If more than one entity meets the FSVP definition of importer for a particular entry, it is important to decide ahead of time which one will serve as the FSVP importer and be identified at entry. o FDA will view that person as the responsible party for meeting all FSVP obligations under the regulation. Changed the text beneath slide to say: We have discussed the importance of properly identifying the FSVP importer at entry. You should now know what

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						information has to be provided to Customs, how to obtain a DUNS number, and how to enter the information at entry. FDA will use this information to oversee the FSVP importer. Ensuring that the appropriate party is entered on CBP entry filing is very important, from a standpoint of ensuring that FSVP obligations have been met, as well as making sure that persons NOT implementing the FSVP requirements are not unknowingly listed as the FSVP importer. Making stable arrangements to designate an appropriate FSVP importer and to confirm that the appropriate person is the ONLY one identified at entry cannot be overemphasized.
PPT, PM	Ch. 8	Slide 17 8-12	All	All	1	Changed previous slide 15 “Chapter 8: Questions” to slide 17.
CHAPTER 9 CHANGES						
PM	Ch. 9	9-1	PP 1	3	1	Bolded the second sentence in the text beneath slide 1 that says: Your performance of every aspect of developing and conducting your FSVP must be documented, and you must make your FSVP records available to FDA promptly upon request.
PPT, PM	Ch. 9	Slide 4 9-3	PP 2	4	1	Changed bullet 3 on slide 4 to say: • Failure to comply with the FSVP record requirements may hinder your ability to import food. Added the word “future” between the word “refuse” and “entry” in the fourth line of text in the second paragraph.
PM	Ch. 9	9-4	PP 1	1		Added the text “As previously noted in Chapter 2,” at the beginning of the first sentence.
PPT, IG, PM	Ch. 9	9-5	All	All	1	Changed the sub-bullets to say: • Hazard analysis

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• Evaluation of foreign supplier performance and risk posed by food • Procedures for approving foreign suppliers • Documentation of foreign supplier approval • Procedures to ensure use of only approved foreign suppliers • Determination of verification activities and frequency • Performance of verification activities • Discussion of any needed corrective actions • Reevaluations of your FSVP, either routinely every 3 years or for cause Changed the text beneath slide to say: The following are records relevant to your foreign supplier that you should maintain, including: • The hazard analysis, • Evaluation of foreign supplier performance and risk posed by the food, • Procedures for approving foreign suppliers, • Documentation of foreign supplier approval, • Procedures to ensure use of only approved foreign suppliers, • Determination of verification activities and their frequency, • Performance of verification activities, • Discussion of any needed corrective actions, and • Reevaluations of your FSVP, either for routinely every 3 years or for cause.
PM	Ch. 9	9-5	KP			Added KP that says: Many importers may want to develop a written program overview document, e.g., Standard Operating Procedures (SOP), that helps explain how all of these records fit together. This may be a useful tool during FDA inspections.

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PPT, PM	Ch. 9	Slide 7 9-6	PP 1	1 & 2	1	Changed slide 7 title to "An Example: Hazard Analysis Records You Need for an FDA Inspection" Unbolded "qualified individual" in bullet 4 on slide. Changed two lines of text beneath slide to say: An example of the hazard analysis records you need for an FDA inspection should include, but not be limited to:
PPT, PM	Ch. 9	Slide 8 9-7	PP 2 & 3	8 (2) & All (3)	1	Added a sub-sub-bullet to the third sub-bullet "Electronic records:" that says: • **Note:** Importers must maintain a system for their electronic records to ensure that the records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. Added an asterisk after "Electronic records" in the fourth list item in paragraph 2 of the text beneath slide. Added a footnote related to the asterisk that says: **Note: Importers should maintain a system for their electronic records to ensure that the records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.*
PM	Ch. 9	9-7	KP			Changed KP to say: If you rely on records prepared by another entity, you still need to retain, sign, and date the records of your qualified individual's assessment of the other entity's records. You should also recognize that, if FDA inspects your records, the agency will need to be able to evaluate whether the original activity (e.g., another entity's hazard analysis) was conducted in a manner that meets FSVP requirements. As an illustration of this, remember that the rule specifies in the case of audits

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						that you are not required to maintain a copy of another entity's audit report, but you must retain documentation of 1) audit procedures, 2) dates of the audit, 3) conclusions of the audit, 4) any corrective actions taken to correct deficiencies, and 5) that the audit was done by a qualified auditor.
PPT, PM	Ch. 9	Slide 9 9-8	All	All	1	Moved slide 9 "Records Must Be Signed and Legible" and related text previously on pages 9-7 & 9-8 to be fully on page 9-8.
PM	Ch. 9	9-8	KP			Added KP that says: The FSVP importer is ultimately responsible for these activities. Each activity must be conducted by an importer's qualified individual (a person who is qualified to conduct the particular activity). The qualified individual is likely either an employee of the importer or acting on behalf of the importer so the qualified individual will sign the records for the importer (who, remember, is most likely a business entity). If the activity is done by someone who is not acting on behalf of the importer (e.g., hazard analysis of the supplier performed by another entity), then the importer, through its qualified individual, has to review and assess that activity and must sign the documentation that they reviewed or assessed it. That assessment would include that they have determined that whoever did that activity is a qualified individual.
PPT, PM	Ch. 9	Slide 10 9-9	All	All	1	Moved slide 10 "Records May Be Maintained in a Language Other Than English" and related text previously on page 9-8 to page 9-9. Changed the first line of the text in the second paragraph to say: FDA explained in the preamble to the final rule that, "Although
PM	Ch. 9	9-9	KP			Added KP that says: FDA states in the preamble to the rule, "We believe that a 'reasonable' time in which to provide translated records would

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						depend on the volume of the records requested, but should not be so long as to impair the Agency's ability to conduct record reviews and follow-up enforcement activities. Without the requirement to translate records in a reasonable time, we would not be able to efficiently enforce section 805 of the FD&C Act."
PM	Ch. 9	9-9	RN			Added RN that says: To review the information regarding records maintained in a language other than English, see Appendix 1, pg. A1-24, sec. 1.510(b)(1).
PPT, PM	Ch. 9	Slide 11 9-10	All	All	1	Moved slide 11 "Records Must Be Available to FDA" and related text previously on page 9-9 to page 9-10.
PPT, PM	Ch. 9	Slide 12 9-11	All	All	1	Moved slide 12 "Offsite Records" and related text previously on page 9-10 to page 9-11. Changed the second paragraph to say: Although FDA is being flexible about offsite records, you need to remember that failure to deliver the records promptly will be considered a violation. If you are unable to deliver your records to FDA within 24 hours, you should communicate with the FDA investigator making the request as soon as possible and discuss a reasonable alternative.
PPT, PM	Ch. 9	Slide 13 9-11	All	All	2	Moved slide 13 "Retaining Records" and related text previously on page 9-10 to pages 9-11 & 9-12. Added a sub-sub-bullet under the second bullet's sub-bullet that says: **Note:** Documentation for "very small importer" eligibility must be retained for at least 3 years. Added second sentence to paragraph 3 of text beneath slide that says:

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						There is also a 3-year retention requirement for documentation of "very small importer" eligibility.
PPT, PM	Ch. 9	Slide 14 9-12	All	All	1	Moved slide 14 "Existing Records for FSVP Purposes" and related text previously on page 9-11 to page 9-12. Changed the first two sentences in the first paragraph of text beneath slide to say: You do not need to duplicate existing food safety-related records if they contain information required for FSVP purposes. However, if your existing records contain only some of the required information, you may maintain any required additional records either separately or combined with the existing records.
PPT, PM	Ch. 9	Slide 15 9-13	All	All	1	Moved slide 15 "Records Provided to FDA May Be Subject to Public Disclosure" and related text previously on page 9-12 to page 9-13. Changed slide title to "Some Records Provided to FDA May Be Subject to Public Disclosure" Changed slide to say: • Under § 1.510(f) of the final rule, FDA states, "records obtained by FDA in accordance with the FSVP regulation will be subject to the public disclosure provisions in part 20 (21 CFR part 20), including the protections against disclosure of trade secrets and commercial or financial information that is privileged or confidential." • Part 20 requires the disclosure, but also contains the exemptions that protect trade secrets and confidential commercial information from disclosure. Changed the second paragraph of text beneath slide to say:

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						The FDA regulations that explain the rules for disclosing records to the public are contained in 21 CFR Part 20 (see link in the Resources textbox to the right of the slide). Part 20 requires the disclosure, but also contains the exemptions that protect trade secrets and confidential commercial information from disclosure.
PPT, PM	Ch. 9	Slide 16 9-14	All	All	1	Moved slide 16 “Importance of Records” and related text previously on page 9-13 to page 9-14. Changed the last sentence in the paragraph of text beneath slide to say: FDA will issue guidance that relates to recordkeeping.
PPT, PM	Ch. 9	Slide 17 9-14	All	All	2	Moved slide 17 “Chapter 9: Summary” and related text previously on page 9-13 to pages 9-14 & 9-15.
PPT, PM	Ch. 9	Slide 18 9-15	All	All	1	Replaced original slide 18 “Chapter 9: Questions” previously on page 9-14 with new slide 18 “Chapter 9 Exercise: “What Records Are Required of FSVP Importers?” on page 9-15. New slide 18 says: • **Timing:** 20 minutes total o 10 minutes to answer the True/False questions. o 10 minutes for instructor to go over the answers and respond to any questions. • **Directions:** Identify what records are required of FSVP importers by selecting true or false at the end of each question (see Chapter 9, page 19, in the Exercise Workbook for the questions). • The instructor will share and discuss the answers after everyone has finished. • You will be given 10 minutes to answer the questions. Added text beneath slide that says:

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						This exercise provides an opportunity not only to reinforce the FSVP records concepts, but also to review some of the other FSVP requirements for which records are required. **Directions:** Identify what records are required of FSVP importers by selecting true or false at the end of each question (see Chapter 9, page 19, in the Exercise Workbook).
CHAPTER 10 CHANGES						
PPT, PM	Ch. 10	Slide 4 10-3				Changed the second bullet on slide 4 to say: • Publish guidance to assist with compliance.
PPT, PM	Ch. 10	Slide 6 10-5	PP 3	5 & 6	1	Added on slide 6 “FDA Compliance Activity for FSVP” a new sub-bullet 1 under bullet 2 that says: • May be delivered by other means, if done promptly. Moved previous sub-bullet 1 to sub-bullet 2. Deleted the third sentence in the third paragraph that said: FDA will elaborate on this in guidance.
PM	Ch. 10	10-6	PP 2	All		Deleted the second paragraph of text beneath slide “What to Expect During an Inspection” that said: It should be noted that records provided to FDA may be subject to public disclosure (although confidential commercial information and certain other non-public information is exempt from disclosure). In this regard, FDA states “[a]lthough we understand concerns about the security of data submitted electronically to the Agency, as well as concerns about confidential commercial information and terrorism, we will take appropriate steps to secure communications with importers and to protect any data we receive, whether submitted electronically or otherwise.”
PM	Ch. 10	10-6	RN			Moved RN previously on page 10-7 to page 10-6.

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PPT, PM	Ch. 10	Slide 8 10-6 & 10-7	All	All	2	Moved slide 8 "Form 482d and 483a" previously on page 10-7 to bottom of page 10-6 with related text on page 10-7. Changed title of slide 8 to "Form FDA 482d and Form FDA 483a"
PM	Ch. 10	10-7	KP			Added KP that says: If you have previously filed a facility registration, you may already have a FURLS account.
PM	Ch. 10	10-8	PP 2 beneath slide	All		Added a transitional sentence to say: Now that you know what an FDA onsite inspection or records review consists of, let's talk about how to prepare for an FDA inspection.
PPT, PM	Ch. 10	Slide 11 10-9			1	Changed the first bullet on slide 11 to say: • Make sure FSVP records are easily accessible and other records can be retrieved within a reasonable timeframe.
PM	Ch. 10	Slide 12 10-9	PP 1	2 & 3	2	Changed the first sentence in the paragraph beneath slide to say: There have been some concerns that FDA will be doing FSVP enforcement at the time food is entered into the U.S., but FDA does not intend to oversee compliance with this rule on a shipment by shipment basis at the time of entry.
PM	Ch. 10	10-9	KP			Changed KP to say: It is important to understand that FDA will not assess FSVP compliance on a shipment by shipment basis during the admissibility process. Rather, FDA will assess the FSVP importer's compliance by reviewing FSVP records at the FSVP importer's place of business in the U.S., as identified through the new data requirements. The only change to entry procedures will be identifying the FSVP importer, as discussed in Chapter 8.

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PPT, PM	Ch. 10	Slide 13 10-10	PP 1	8 & 9	1	Changed bullet 3 on slide 13 "What to Do When FDA Notifies You of an Inspection" to say: • Be prepared to discuss any corrective actions necessary to correct any deficiencies, including establishing an acceptable timeframe for completing the corrective actions. Changed list item 3 in the paragraph beneath slide to say: • Be prepared to discuss any corrective actions necessary to correct any deficiencies, including establishing an acceptable timeframe for completing the corrective actions.
PM	Ch. 10	10-11	PP 1	2 & 3	1	Changed the second sentence in the text beneath slide to say: In most cases when there is not an imminent health threat, FDA is expected to send warning letters to importers who are not in compliance with FSVP requirements and have failed to take appropriate corrective action.
PPT, PM	Ch. 10	Slide 15 10-11 & 10-12	All	All	2	Changed slide 15 "What Are FDA's Legal Enforcement Tools if I Don't Comply with FSVP?" to say: • FDA has authority to detain an imported food (possibly followed by a refusal of its entry into the U.S. under section 801(a)(3) of the FD&C Act: o If it appears to FDA that you, as the importer of the food, have failed to meet FSVP requirements; o **Note:** Your food may also be subject to refusal if it does not comply with other FD&C Act requirements. • When a food is offered for importation into the U.S., U.S. Customs and Border Protection (CBP) will transmit the information to FDA. If a U.S. entity is not identified as the importer for purposes of FSVP, the import information will be rejected (Sec. 1.514).

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						o The filer will receive an error message and will be able to offer adjustments and resubmit Changed the text beneath slide to say: The food you import is subject to detention (possibly followed by refusal of admission into the U.S.) under section 801(a)(3) of the FD&C Act, if it appears to FDA that you, as the importer of the food, have failed to comply with the FSVP requirements (your food may also be subject to refusal if it does not comply with other FD&C Act requirements). Section 1.514 of the FSVP rule focuses on what happens if the importer does not comply with the FSVP rule. When a food is offered for importation into the U.S., U.S. Customs and Border Protection (CBP) will transmit the information to FDA. If a U.S. entity is not identified as the importer for purposes of FSVP, the import information will be rejected, which will generate an error message, so the filer can make appropriate adjustments and resubmit the entry line. **As mentioned earlier, FDA initially wishes to focus on educating food importers and the entire food-importing sector about the FSVP requirements. Nevertheless, FDA will be inspecting U.S.-based FSVP importers and examining their records to assess their compliance efforts, and FDA has stated that the agency will act swiftly when appropriate. Note that FDA has stated that, "[a]s with all of our FSMA-related enforcement efforts, we intend to apply our FSVP enforcement resources in a risk-based manner, placing greater emphasis on violations of the regulation that are more likely to result in harm to public health." If FDA finds violations that pose a risk to public health, the agency will use its enforcement authorities to protect consumers.**

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PPT, PM	Ch. 10	Slide 16 10-12 & 10-13	All	All	1	Moved slide 16 “Additional FDA Enforcement Tools” and related text previously on page 10-14 to pages 10-12 & 10-13. Changed slide 16 “Additional FDA Enforcement Tools” to say: • FDA has the authority to place your violative food on import alert so that future shipments of the food would be Detained Without Physical Examination (DWPE). • FDA also has the authority to take action against your food after it has entered the U.S., if it violates the adulteration or allergen labeling provisions of FD&C Act. FDA authority includes: o Requiring the recall of harmful food in U.S. commerce (along with warning consumers not to consume the food), and o Administratively detaining harmful food in domestic commerce while initiating an action to seize (and possibly destroy) the food. Changed the paragraphs 3 & 4, and added paragraph 5 beneath slide to say: Also, as FDA clarified in the rule preamble “...when we identify violations with respect to products, shippers, and/or importers, we may place the products, shippers, and/or importers on an import alert. Import alerts provide guidance to FDA field staff that future shipments appear violative within the meaning of applicable FD&C Act provisions. Based on information in an import alert, field staff might detain products in shipments without physical examination.” When a product is detained without physical examination, the burden shifts to the importer to demonstrate that each shipment of the product is in compliance. “Our [FDA’s] decisions to remove an importer from an import alert are based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and we have confidence that future

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						entries will be in compliance with the relevant FD&C Act requirements." Although FDA's oversight of FSVP compliance will not be focused at the time of entry of food into U.S. commerce, as mentioned earlier, FDA will be inspecting FSVP importers and examining their records. If FDA determines that FSVP requirements are not being met, there can be consequences, as noted above, that would impact that importer's ability to import foods. Most of FDA enforcement tools are not specific to FSVP. They pertain to actions against the food and actions against a person/company. Several are set forth in the previous slide and here. For any action taken, FDA would cite the provision(s) of the regulation and FD&C Act that were violated. As always, opportunity to demonstrate compliance is provided.
PPT, PM	Ch. 10	Slide 17 10-14	All	All	1	Moved slide 17 "FSVP Compliance Dates Are Being Phased In" and related text previously on page 10-15 to page 10-14.
PPT, PM	Ch. 10	10-14	KP			Added a fourth paragraph to KP that says: For more information on Compliance Date Extensions and Clarifications for FSMA Final Rules, see Appendix 2 in this manual or review the extended compliance dates available on FDA's website at: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm517545.htm
PPT, PM	Ch. 10	Slide 18 10-14 & 10-15	All	All	2	Moved slide 18 "Compliance Dates for FSVP Importers" and related text previously on page 10-15 to page 10-14. Changed slide 18 "Compliance Dates for FSVP Importers" to say:

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						• The first compliance date for FSVP importers was May 30, 2017. o This applied to importers of food from the largest processing facilities that are subject to the PC rule, as well as food that is not subject to either the PC or Produce Safety rule. • The various compliance dates for the FSVP rule are listed in Appendix 2 of the Participant Manual. Changed the paragraph of text beneath slide to say: The FDA website states that the compliance dates for FSVP vary according to a number of different factors relating to the nature of the importer, the size of the foreign supplier and the type of food imported. The FSVP website does not include dates for importers that are themselves a manufacturer or processor subject to the supply-chain program provisions in the PC rules. Importers who choose to comply with the supply chain provisions of the PC rule, rather than most of the FSVP requirements, should consult those rules for their compliance dates. The compliance dates for the FSVP rule are listed in Appendix 2.
PPT, PM	Ch. 10	Slide 19 10-15	All	All	1	Moved slide 19 “Chapter 10: Summary” and related text previously on page 10-16 to page 10-15. Changed the last two sentences in the paragraph beneath slide to say: The chapter, while indicating the seriousness of not complying with the rule, has tried to indicate that there will be a transitional period where FDA will be emphasizing education to bring importers, as well as others in the supply chain, into compliance. However, this transitional period will not continue forever so it is important that you understand the requirements and comply fully.

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PPT, PM	Ch. 10	Slide 20 10-16	All	All	1	Moved slide 20 “Chapter 10: Questions” and related text previously on page 10-17 to page 10-16.
APPENDIX 1 CHANGES						
PM	App. 1					Changed appendix title “Appendix 1: FSVP Summary and Rule” to “Appendix 1: FSVP Summary, Rule, and Guidance”
PM	App. 1	A1-1				**Appendix 1 TOC:** Added sub-header “Related Guidance” and guidance documents as bullet points to the App. 1 TOC: Related Guidance • Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation (page A1-37) • Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation (page A1-41) • FDA Guidances Explain Certain Exemptions from FSMA (page A1-45) • Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA (page A1-47)
PM	App. 1	A1-3 to A1-9				Replaced “FSVP Final Rule Summary (for reference only)” with updated information from FDA’s Website.
PM	App. 1	A1-11 to A1-35				Added page breaks to “FSVP Final Rule” so that the regulation page headers are at the top of the page.
PM	App. 1	A1-37 to A1-39				Added “Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation (for reference only)” document from FDA’s Website.

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PM	App. 1	A1-41 to A1-44				Added "Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation (for reference only)" document from FDA's Website.
PM	App. 1	A1-45				Added "FDA Guidances Explain Certain Exemptions from FSMA (for reference only)" from FDA's Website.
PM	App. 1	A1-47 to A1-56				Added "Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA (for reference only)" from FDA's Website.
APPENDIX 2 CHANGES						
PM	App. 2	A2-3 to A2-4				Replaced "Compliance Dates for the Final Rule on Foreign Supplier Verification Programs (FSVP) (for reference only)" with updated information from FDA's Website.
PM	App. 2	A2-5 to A2-7				Replaced "Compliance Date Extensions and Clarifications for FSMA Final Rules (for reference only)" with updated information from FDA's Website.
APPENDIX 3 CHANGES						
PM	App. 3	A3-1				**Appendix 3 TOC:** Changed "Workaid C: Summary of FSVP Process Requirements" to "Workaid C: Summary of FSVP Requirements" Added new Workaids as noted below: Workaid D: FSVP Hazard Analysis Form Example (page A3-13) Workaid E: FSVP Foreign Supplier Evaluation Form Example (page A3-15) Workaid F: FSVP Foreign Supplier Performance/Food Product Approval Worksheet Example (page A3-17)

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						Workaid G: FSVP Foreign Supplier Reevaluation Form Example (page A3-19)
PM	App. 3	A3-3				**Workaid A: "Determining the FSVP Importer"** Changed the "Instructions" to say: This workaid is intended to help a person/entity who receives/sells imported food to ensure that an appropriate FSVP importer has been designated by parties involved in the importation of the food AND that the U.S. Customs and Border Protection (CBP) filer enters that name, email address, and DUNs number as the FSVP importer. Added category headers: • Imported Food(s)/ Food Product(s) Information • Supplier Information • Determining FSVP Importer • Designated FSVP Importer* • CBP Entry Filer Changed the column headers to say: • Column 1: What food(s)/ food product(s) do you Import (receive)? [Note: List each food/food product. Be specific, e.g., can sizes; size packages; bulk weight] • Column 2: For each food listed, will the food or food product made from the imported food be offered for sale in the U.S.? • Column 3: From whom do you purchase the food (i.e., supplier's name, address, etc.)? • Column 4: Is the supplier a U.S. company or a foreign company? • Column 5: Does the person/company from whom you directly purchase the food fit the FSVP definition of foreign supplier (i.e., grower, manufacturer)?

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						• Column 6: Describe the current buying arrangement (s) (i.e., name all parties involved in obtaining the food product, including foreign supplier, if known) • Column 7: At time of entry, do you own the food, or have you purchased or agreed to purchase the food (i.e., do you fit the definition of "U.S. owner or consignee" and therefore, FSVP "importer" for this food)?** • Column 8: Who else involved in this arrangement fits the FSVP definition of importer? [Note: Be specific, e.g., are there multiple purchasers for the same line entry of food, do you purchase food from a U.S. importer/distributor?] • Column 9: If more than one person/entity fits the definition of importer, negotiate with others to determine who will carry out FSVP requirements. [Note: Place name below and formalize the understanding (i.e., create an agreement identifying FSVP importer)] • Column 10: Who fills out CBP entry filing for this food/food product (i.e., name, address)? [Note: Provide copy of agreement/understanding identifying the FSVP Importer* to be identified in CBP entry filing (i.e., name, address, email, and DUNS number of agreed upon FSVP importer)] Added two footnotes that say: *The person identified as the FSVP "importer" in the CBP entry filing is the person FDA will see as responsible for complying with the FSVP rule. **You would also meet the definition of FSVP importer if there is no U.S. owner or consignee at time of entry and you are the U.S. agent or representative of the foreign owner or consignee.

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PM	App. 3	A3-5 to A3-7				**Workaid B: "FSVP Requirements Based on What You Import, If You Are a Very Small Importer (VSI), or If You Import from Certain Foreign Suppliers" changed as noted below:** **Foods Not Subject to FSVP:** A. Deleted the words "for importer" after "requirements" and before "in the Seafood…." C. Changed the word "Products" to "Alcoholic beverages" before "must" at the start of the second sentence. Changed the last sentence to say: "In addition, exemption applies for imported raw materials and other ingredients you use in manufacturing/processing, packing, or holding alcoholic beverages in certain circumstances." D. Changed the paragraph to say: Food for Personal Consumption, Research, or Evaluation (food should be imported in small quantities consistent with such uses and must not be sold or distributed to the public; if the food is for research or evaluation, it must also be labeled as such and have electronic declaration that the food will be used for research or evaluation) F. Added new "F" that says: U.S. Food Returned (i.e., food manufactured/processed, raised, or grown in U.S., exported, and returned without further manufacturing/processing)

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						G. Added the words “at time of entry” after “Service” and before “(subject to…)” **Importers Subject to FSVP Modified Requirements:** A. Changed “biannual” to “biennial” in the third line of text B. Changed the paragraph to say: Importer importing from certain small foreign suppliers (foreign supplier must qualify for one of 3 categories (<3000 laying hens, “qualified facility” or not a “covered farm” under 21 CFR 112.4(a) or 112.4(b) and 112.5); confirm eligibility on an annual basis; biennially obtain written assurance that supplier is complying with U.S. food safety requirements (or, for non-covered farms or small shell egg producers, acknowledgement that food must not be adulterated); also must evaluate, approve, and periodically reevaluate suppliers, and have procedures to ensure use of approved suppliers) C. Added the word “compliance” after “good” and before “standing” **Additional Food Categories with Non-Standard Requirements:** C. Added the words “of the LACF” after “manufacturer/processor” and before “must…” in next to the last line of text D. Changed the text to say: Food ingredients going to U.S. manufacturing/processing facility subject to Preventive Controls regulations: If importer implements preventive controls for the hazards in

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						foods in compliance with applicable PC requirement (i.e., either § 117.135 or §507.34), then FDA deems importer in compliance with FSVP, but manufacturer/processor must be identified as FSVP importer at entry under § 1.509. Importer also deemed in compliance with most of FSVP if it: (1) is not required to implement a preventive control because its customer or a subsequent entity is controlling the hazard under § 117.136 or § 507.36; or (2) it has established a supply-chain program for the food under subpart G of part 117 or subpart E of part 507. E. Changed the text to say: Food products not intended for further processing (all "standard" FSVP requirements apply) (provided the importer is not a very small importer and is not obtaining food from certain small foreign suppliers) 1. Added the words "at time of entry," after "Acts" and before "such as…"
PM	App. 3	A3-9 to A3-12				**Workaid C: "Summary of FSVP Process Requirements" changed as noted below:** Changed title to "Summary of FSVP Requirements" **General:** Changed sentence 2 & 3 of Item 1, under General to say: The QI may be an employee of the importer or not. More than one QI may be involved in performing the FSVP activities. If the importer is depending on a third party's hazard evaluation, verification or other steps in FSVP activities (other than supplier approval, which must be performed directly by the importer), the importer must ensure that the third party used a QI to carry out that activity and the importer's QI must review and assess that information and find it acceptable.

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						Changed sentence 2 & 3 of Item 2, under General to say: The importer is required to keep adequate records for at least two years after an activity is completed or the record is no longer used. Even when the importer is relying on a third party's HA, foreign supplier evaluation, verification determination, or another activity, the importer must document its review and assessment of the other party's information. Capitalized the word "Agency" in the last sentence in the text Deleted the word "Process between "FSVP" and "Steps in the second section title to say: **"Specific FSVP Steps (dependent on type of food imported, importer size, certain foreign supplier types/sizes, and comparability/equivalence standing of originating country):"** 1. Hazard Analysis: a. Added the words "information on" after "approvals," and before "major allergens…" 2. Evaluation for foreign supplier approval and verification: Changed the word "hazards" to "hazard" in line three of the text 3. Foreign Supplier Approval: Added the word "the" after "…posed by" and before "food." In line 3 of the text 4. Verification Activities: a. Deleted the parentheses around the sentence "If circumstances require use of an unapproved foreign supplier on temporary basis, importer must still subject that foreign

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						supplier's food to adequate verification before importing. b. Added the word "the" after "…mentioned in" and before "rule are…" in next to the last line of text c. Replaced the word "ensure" with "provides assurance" in the first line of text Important Notations: a. Added the words "to import the food under certain modified FSVP requirements," after "…U.S.," and before "the importer" in the third line of text Added the word "compliance" after "good" and before "standing in the last line of text
PM	App. 3	A3-13				Added new "Workaid D: FSVP Food Hazard Analysis (HA) Form Example"
PM	App. 3	A3-15				Added new "Workaid E: FSVP Foreign Supplier Evaluation Form Example"
PM	App. 3	A3-17				Added new "Workaid F: FSVP Foreign Supplier Verification Activity(ies) Worksheet Example"
PM	App. 3	A3-19 to A3-20				Added new "Workaid G: FSVP Foreign Supplier Reevaluation Form Example"
APPENDIX 4 CHANGES						
PM	App. 4	A4-1				**Appendix 4 TOC:** Changed Objectives to say: Learning Objectives: • By the end of this chapter, participants will be able to: 1. Define "dietary supplement."

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						2. Explain the importance of the CGMP for dietary supplements. 3. Describe FSVP responsibilities whether you import dietary supplement components or finished dietary supplements. 4. Describe how FSVP requirements for dietary supplements and dietary supplement components differ from other foods.
PPT, PM	App. 4	Slide 2 A4-4	PP 1	5-7	1	Changed Learning Objectives 2, 3, & 4 on slide to say: 2. Explain the importance of the CGMP for dietary supplements. 3. Describe FSVP responsibilities whether you import dietary supplement components or finished dietary supplements. 4. Describe how FSVP requirements for dietary supplements and dietary supplement components differ from other foods. Changed list items 2, 3, & 4 in text beneath slide to say: 2. Explain the importance of the CGMP for dietary supplements. 3. Describe FSVP responsibilities whether you import DS components or finished dietary supplements. 4. Describe how FSVP requirements for dietary supplements and dietary supplement components differ from other foods.
PM	App. 4	A4-5	PP 1	3 & 4		Added new sentence at the end of paragraph 1 to say: In the U.S. dietary supplements are only for human use and not animal use.
PPT, PM	App. 4	Slide 5 A4-7	All	All	1	Added new slide 5 “Manufacturers of Dietary Supplements and Their Components Are Subject to CGMP Requirements” that says:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• Facilities that manufacture dietary supplements and dietary supplement components must be in compliance with the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (DS CGMP) in 21 CFR Part 111 and adverse event reporting. o Exempt from FSMA Preventive Controls requirements. • The DS CGMP regulation contains “specification” requirements that contain supplier verification provisions, requiring: o Properly identified ingredients; o Ingredients of appropriate purity, strength, and composition; and o No contamination of ingredients that adulterate or could lead to adulteration. Added new text beneath slide that says: In publishing the DS CGMP in 2007, FDA stated that “consumers should have access to dietary supplements that meet quality standards and that are free from contamination and are accurately labeled.” The CGMP applies to all domestic and foreign companies that manufacture, package, label, or hold dietary supplements, including those involved with the activities of testing, quality control, packaging, and labeling, and distributing them in the U.S. Because the CGMP address the hazards applicable to dietary supplements, these products are exempt from the PC rule. The CGMP contains "specification" requirements that address supplier controls. Under these requirements, the dietary supplement manufacturer must ensure that all ingredients are

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						properly identified; of appropriate purity, strength, and composition; and are not contaminated in a way that can adulterate the dietary supplement.
PPT, PM	App. 4	Slide 6 A4-8 & A4-9	All	All	1	Moved previous slide 5 “Importance of DS CGMPs” and related text previously on page A4-7 to pages A4-8 & A4-9 and changed the title to “Importers of Dietary Supplements and Their Components Are Subject to Modified FSVP Requirements” Changed slide to say: • FDA tied the FSVP requirements for importers of dietary supplements to the DS CGMP. • Importers of dietary supplements and dietary supplement components that will undergo further processing (by importer or other customer) are subject to limited FSVP requirements because the "specification" requirements already contain supplier verification provisions. • Importers of finished dietary supplements must follow FSVP requirements that are similar to the requirements for importers of other foods, except: o The importer must verify their suppliers' compliance with DS CGMP, and o No hazard analysis is required. Changed the text beneath slide to say: By way of background, FDA wanted to assure that the FSVP requirements for dietary supplements and their components) reflected the manner in which such products are regulated. **Thus, the focus continues to be on the manufacturers’ compliance with the *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements* (DS CGMP) regulation (21 CFR Part 111), rather than on verifying hazards you identify, as with the standard FSVP**

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						provisions. So, the basic task of FSVP importers is to verify that foreign suppliers are complying with the DS CGMP requirements. It is assumed that compliance with those regulations will ensure the safety of dietary supplements. Therefore, while dietary supplements are subject to FSVP requirements, they are modified requirements. For example, because dietary supplements and dietary supplement components that require further processing after importation will be subject to the supplier verification provision in the CGMP regulations, there would be little added benefit to requiring a redundant supplier verification under FSVP. FDA developed "modified" FSVP requirements that are tailored for dietary supplements. These modified requirements focus on manufacturers' compliance with the dietary supplement CGMP regulation, rather than on verification of hazard control (which is the focus of the "standard" FSVP requirements). In addition, there are FSVP requirements for two types of importers of dietary supplements: • Importers who must (or whose customers must) establish certain specifications under the CGMP (e.g., for components or packaging) and ensure that the specifications are met (thereby performing a kind of "verification" of a dietary supplement or dietary supplement component). The only FSVP requirements for these importers are to use a qualified individual and ensure that the importer is identified as the importer at entry (and, if the importer's customer is establishing and verifying conformance to a specification, obtain written assurance from the customer); and • Importers of all other dietary supplements (e.g., "finished" dietary supplements), who are not required to conduct a hazard analysis and whose verification

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						activities must provide assurances of the manufacturer's compliance with dietary supplement CGMP.
PPT, PM	App. 4					Deleted previous slide 6 "FSVP Requirements for Dietary Supplements" and related text.
PPT, PM	App. 4	Slide 7 A4-9 & A4-10	All	All	1	Changed slide 7 "Dietary Supplement Manufacturer/Processor Importing DS Components" to "Scenario 1: Dietary Supplement Manufacturer/Processor Importing Dietary Supplement Components" Changed slide to say: • If you are: o An importer of dietary supplement components, and o A dietary supplements manufacturer or processor (Note: packaging and labeling is considered processing), and o You are complying with the DS CGMP (including the requirements relating to specifications) in 21 CFR 111.70(b) or (d), • Then you have met your main FSVP obligations and only minimal documentation is required.
PPT, PM	App. 4	Slide 8 A4-10	All	All	1	Changed slide 8 "Dietary Supplement Manufacturer/Processor Importing DS Components (continued)" to "Scenario 1: Dietary Supplement Manufacturer/Processor Importing Dietary Supplement Components (continued)"
PPT, PM	App. 4	Slide 9 A4-11	All	All	1	Changed slide 9 "Dietary Supplement Manufacturer/Processor Importing DS Components (continued)" to "Scenario 1: Dietary Supplement Manufacturer/Processor Importing Dietary Supplement Components (continued)" and moved previously on page A4-10 to page A4-11. Changed bullet 2 to say:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• Your finished dietary supplement components must comply with all requirements in the DS CGMP rule and other FDA requirements. Changed the text beneath slide 9 to say: To be clear, in this scenario you are not required to comply with the other FSVP requirements such as the hazard analysis, evaluation of foreign suppliers and verification activities. Your finished dietary supplements must, of course, comply with all requirements in the DS CGMP rule and other FDA requirements such as the nutrition labeling requirements for dietary supplements.
PPT, PM	App. 4	Slide 10 A4-11 & A4-12	All	All	2	Changed slide 10 “Dietary Supplement Manufacturer/Processor Importing DS Components (continued)” to “Scenario 1: Dietary Supplement Manufacturer/Processor Importing Dietary Supplement Components (continued)” and moved text to bottom of A4-11 and top of A4-12.
PPT, PM	App. 4	Slide 11 A4-12			1	Changed slide 11 “FSVP Requirements for Other DS Products” to “Scenario 3: FSVP Requirements for Finished Dietary Supplements” Unbolded “qualified individual” in the first sub-bullet under the fourth bullet.
PPT, PM	App. 4	Slide 12 A4-13			1	Changed slide 12 “What About Performance by Others?” to “Can Others Conduct Supplier Verification Activities?” Unbolded “qualified individual” in the sub-bullet under the third bullet.
PPT, PM	App. 4	Slide 13 A4-14			1	Changed slide 13 “What Safety Assurance Is Needed” to “What Must I Verify?” Changed the first bullet to say:

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						• Your foreign supplier verification activities for imported dietary supplements or dietary supplement components must:
PPT, PM	App. 4	Slide 14 A4-14 & A4-15	PP 1	4-8	2	Changed slide 14 “Appendix 4: Summary” bullet 2 to say: • If you import finished dietary supplements: o You must conduct most of the standard FSVP activities explained in other FSVP chapters, and o You must verify compliance with the DS CGMP requirements in 21 CFR Part 111, but o You are not required to conduct a hazard analysis. Changed the second bullet in text beneath slide (top of page A4-15) to say: • If you import finished dietary supplements or dietary supplement components, you are not required to conduct a hazard analysis and your foreign supplier verification activities are to determine compliance with is tied to the DS CGMP in 21 CFR Part 111.
PPT, PM	App. 4	Slide 15 A4-15	All	All	1	Changed slide 15 “Appendix 4: Summary (continued)” to say: • If you are an importer that manufactures/processes dietary supplements, and: o You have established that your specifications for dietary supplement components/safe packaging and labeling have been met (21 CFR 111.70(b) or (d)), o You have met most of your FSVP requirements. • If your customer is required to establish specifications for dietary supplement components under DS CGMP, and has established that specifications are met:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						○ You must annually obtain from your customer written assurance that it is in compliance with those requirements. Changed the text beneath slide to say: • If you are an importer that manufactures/processes dietary supplements, and you have established that your specifications for dietary supplement components/safe packaging and labeling have been met (21 CFR 111.70(b) or (d)), you have met most of your FSVP requirements. • If your customer is required to establish specifications for dietary supplement components under the DS CGMP and have established that specifications are met, you must annually obtain from your customer written assurance that it is in compliance with those requirements.
PPT, PM	App. 4	Slide 16 A4-16	All	All	1	Added new slide 16 “Appendix 4: Summary (continued)” that says: • If you import finished dietary supplements or supplement components, you must ○ Be identified as the FSVP importer on the CBP entry filings, ○ Use qualified individuals to perform FSVP tasks, and ○ Maintain records in accordance with FSVP requirements. Added new text beneath slide that says: • If you import finished dietary supplements or supplement components, you must ○ Use qualified individuals to perform FSVP tasks, ○ Maintain records in accordance with FSVP

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						o requirements, and o Be identified as the FSVP importer on the U.S. Customs and Border Protection (CBP) entry filings.
PPT, PM	App. 4	Slide 17 A-4-16			2	Moved previous slide 16 “Appendix 4: Questions” to become slide 17 on the bottom of page A4-16.
APPENDIX 5 CHANGES						
PM	App. 5	A5-1				**Appendix 5 TOC:** Changed Learning Objective 4 to say: Describe requirements if they are not a “very small importer,” but are importing from a “certain small foreign supplier.”
PPT, PM	App. 5	Slide 2 A5-4	PP 1	6 & 7	1	Changed Learning Objective 4 on slide 2 “Appendix 5: Goal and Objectives” to say: Describe requirements if they are not a “very small importer,” but are importing from “certain small foreign suppliers.” Changed list item 2 in the text beneath slide to say: The requirements if you are not a “very small importer,” but are importing from “certain small foreign suppliers,” and
PPT, PM	App. 5	Slide 3 A5-5	All	All	1	Moved slide 3 “Modified Requirements” previously on pages A5-4 & A5-5 to page A5-5. Changed slide 3 to say: • Some importers and/or their foreign suppliers may meet criteria that allow for modified FSVP requirements. • The importers and/or the foreign supplier must demonstrate/document that they meet the eligibility criteria • Modified FSVP requirements apply: o If the importer is a “very small importer,”

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						o If the imported food is from “certain small foreign suppliers,” o If the imported food is from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” for certain foods under Systems Recognition, or o If the importer imports dietary supplements or dietary supplement components (see Appendix 4). Changed the text beneath slide to say: Up to this point we have focused on the standard requirements of the FSVP rule. There are instances, however, where an FSVP importer is able to follow modified requirements. Modified FSVP requirements apply if you are a “very small importer” and if you are importing foods from “certain small foreign suppliers” (21 CFR 1.512(a)). Modified requirements also apply if the FSVP importer is importing food from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” for certain foods under Systems Recognition. And finally, modified requirements apply if the FSVP importer is importing dietary supplements or dietary supplement components. Importers or foreign suppliers must first meet the criteria to qualify for modified requirements and must continue to demonstrate their eligibility for these programs. Also, importers that do qualify can decide whether they wish to follow the standard requirements or the modified requirements. We will cover the first three situations in more detail in the next few slides.
PM	App. 5	A5-5	KP			Added KP that says:

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						More details are provided within this appendix, but in general, Importers who are eligible for the modified requirement do not have to do the standard hazard analysis, evaluation of the supplier, or verification activities. However, they still must have a modified FSVP program that includes: • Documentation of eligibility; • Use of a qualified individual for each activity; • Identification of the FSVP importer at entry; and • Obtaining written assurance, as described below in this appendix.
PM	App. 5	A5-5	RN			Added RN that says: For more information on the dietary supplement modified requirements, see Appendix 4 of this manual.
PPT, PM	App. 5	Slide 4 A5-6 & A5-7	All	All	1	Moved slide 4 "'Very Small Importers' and 'Certain Small Foreign Suppliers'" and related text previously on pages A5-5 & A5-6 to pages A5-6 & A5-7.
PPT, PM	App. 5	Slide 5 A5-7	All	All	1	Moved slide 5 "What Is a 'Very Small Importer'?" and related text previously on page A5-6 to page A5-7. Added a new sentence at the end of the second paragraph of text that says: FDA has published charts to help with this: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm
PPT, PM	App. 5	Slide 6 A5-8	All	All	1	Moved slide 6 "Do You Qualify as a 'Very Small Importer'?" and related text previously on page A5-7 to page A5-8.
PPT, PM	App. 5	Slide 7 A5-9	All	All	1	Moved previous slide 8 "Documenting Your Status as a 'Very Small Importer'" and related text previously on page A5-8 to slide 7 on page A5-9.

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PPT, PM	App. 5	Slide 8 A5-9 & A5-10	All	All	2	Moved previous slide 9 "Modified Requirements for 'Very Small Importers'" and related text previously on page A5-9 to slide 8 on pages A5-9 & A5-10.
PPT, PM	App. 5	Slide 9 A5-10	All	All	1	Added new side 9 "Modified Requirements for "Very Small Importers" (continued)" that says: • Additionally, you must: o Identify the FSVP importer for each line entry of food product presented for entry into the U.S. (more details provided in Chapter 8) o Use a qualified individual for each activity o Promptly take corrective actions, if you determine that a foreign supplier of food you import does not produce the food consistent with the written assurances (more details are provided later in this chapter and in Chapter 7) o Maintain records and documentation that demonstrate your compliance with applicable FSVP requirements (more details are provided later in this chapter and in Chapter 9) Added new text beneath slide 9 that says: Along with obtaining written assurances, you must also identify as the FSVP importer for each line entry of food presented for entry into the U.S.; use a qualified individual for each activity; promptly take corrective actions, if you determine that a foreign supplier of food you import does not produce the food consistent with the written assurances; and maintain records and documentation that demonstrate your compliance with applicable FSVP requirements. More details will be provided later in this chapter and in Chapters 8, 9, and 10 respectively.

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PPT, PM	App. 5	Slide 10 A5-11	All	All	1	Moved previous slide 8 "What Are 'Certain Small Foreign Suppliers'?" and related text previously on page A5-8 to page A5-11. Changed last sentence of text beneath slide to say: We will cover each of these three categories in more detail in upcoming slides.
PPT, PM	App. 5	Slide 11 A5-12	All	All	1	Moved previous slide 10 "Importing from 'Certain Small Foreign Suppliers'" and related text previously on page A5-10 to page A5-12. Changed the sub-bullet to say: • Obtain written assurance that your foreign supplier meets the specified criteria for one of the three categories before approving the supplier and each applicable calendar year thereafter. Changed the paragraph beneath slide to say: If you are importing food from one of the three categories of small foreign suppliers and you wish to be subject to the modified (simpler) FSVP requirements, you must obtain written assurance that your foreign supplier meets the specified criteria for one of the three categories **before approving the supplier and annually thereafter by the end of each calendar year.**
PPT, PM	App. 5	Slide 12 A5-12 & A5-13	All	All	2	Moved previous slide 11 "What Are 'Certain Small Foreign Suppliers': 'Qualified Facilities'?" and related text previously on page A5-11 to pages A5-12 & A5-13.
PPT, PM	App. 5	Slide 13 A5-13 & A5-14	All	All	1	Moved previous slide 12 "'Certain Small Foreign Suppliers': 'Qualified Facilities' (continued)" and related text previously on page A5-12 to pages A5-13 & A5-14.

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						Changed title of slide to "Modified Requirements for "'Certain Small Foreign Suppliers': 'Qualified Facilities'"
PPT, PM	App. 5	Slide 14 A5-14	All	All	1	Moved previous slide 13 "What Are 'Certain Small Foreign Suppliers': Farms That Grows Produce?" and related text previously on page A5-13 to page A5-14. Changed title of slide to "What Are 'Certain Small Foreign Suppliers': Farms That Grows Produce?" Changed second sub-bullet to say: • The monetary value of produce sold directly to consumers (or sold to restaurants or retailers within 275 miles) exceeds that sold to other purchasers and the average annual value of all food sold is less than U.S. $500,000.
PPT, PM	App. 5	Slide 15 A5-15	All	All	1	Moved previous slide 14 "'Certain Small Foreign Suppliers': Farms That Grows Produce? (continued)" and related text previously on page A5-14 to page A5-15. Changed title of slide to "Modified Requirements for 'Certain Small Foreign Suppliers': Farms That Grows Produce"
PPT, PM	App. 5	Slide 16 A5-16	All	All	1	Moved previous slide 15 "'Certain Small Foreign Suppliers': Shell Egg Producers" and related text previously on pages A5-14 & A5-15 to page A5-16.
PPT, PM	App. 5	Slide 17 A5-17	All	All	1	Combined and changed previous slides 18 to 23 "If You Are Not a 'Very Small Importer,' but Import from 'Certain Small Foreign Suppliers'" and "If You Are Not a 'Very Small Importer,' but Import from 'Certain Small Foreign Suppliers' (continued)" respectively, and related text previously on pages A5-17 to A5-20 to create slide 17 "What If the FSVP Importer Is Not a 'Very Small Importer,' but Imports from 'Certain Small Foreign Suppliers'?" that says:

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						• If the FSVP importer does NOT qualify as a "very small importer," but does import from "certain small foreign suppliers," the importer must: o Evaluate the foreign supplier's compliance history with applicable food safety regulations (i.e., whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action) and you: ▪ Must reevaluate your supplier when concerns arise or at least every 3 years. ▪ May review and assess another's evaluation or reevaluation. ▪ Must document all evaluations and reevaluations. • Approve the foreign supplier, and • Establish and follow written procedures for ensuring that you only import foods from approved foreign suppliers. o You may rely on another to establish, follow, and document these procedures if you review and assess them. Combined and changed text beneath slide 17 to say: If the FSVP importer is NOT a "very small importer," but does import from "certain small foreign suppliers," the importer must evaluate the foreign supplier's compliance history, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety. You must reevaluate the supplier when concerns arise or at least every 3 years. You can rely on another to evaluate or reevaluate the supplier, as long as you review and assess the evaluation or reevaluation. In addition, you must approve the foreign supplier on the basis of this evaluation. You must

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						also establish and follow written procedures to ensure that you are only importing food only from approved foreign suppliers. You may rely on others to do this as long as you review and assess their procedures.
PPT, PM	App. 5	Slide 18 A5-18	All	All	1	Moved previous slide 16 “What If I Find Assurances Are Invalid?” and related text previously on page A5-15 to page A5-18.
PPT, PM	App. 5	Slide 19 A5-18 & A5-19	All	All	2	Moved previous slide 17 “What Are Appropriate Corrective Actions?” and related text previously on page A5-16 to pages A5-18 & A5-19. Combined the two paragraphs of text beneath slide to make one paragraph.
PPT, PM	App. 5	Slide 20 A5-19	All	All	1	Moved previous slide 24 “Record Keeping Requirements” and related text previously on page A5-20 to page A5-19. Combined the two paragraphs of text beneath slide to make one paragraph.
PPT, PM	App. 5	Slide 21 A5-20	All	All	1	Moved previous slide 25 “FSVP When Food is from a Recognized System” and related text previously on page A5-21 to page A5-20. Changed title of slide 21 to “When Food Is Produced Under a Food Safety System Recognized by FDA” Changed the first bullet and sub-bullets to say: • If you import foods from a foreign supplier in a country with food safety systems recognized by FDA as “comparable” for certain foods under Systems Recognition, your requirements can be reduced if: o The food is within the scope of the Systems Recognition arrangement;

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						o Your supplier is under the regulatory oversight of that food safety authority; and o The supplier must be in good compliance standing. Changed the text beneath slide to say: Over time FDA is expected to evaluate whether other countries have food safety systems that effectively provide the same level of public health protection as that provided by the U.S. system. Countries currently recognized by FDA as having food safety systems comparable to the U.S. are New Zealand, Canada, and Australia. Information on the Australia's recognition with links to the evaluation process can be found on the FDA website at: https://www.fda.gov/food/newsevents/constituentupdates/ucm553382.htm If FDA officially determines that another country's food safety system is comparable for certain foods under Systems Recognition, and if your foreign supplier is providing food that is within the scope of that official recognition and under the jurisdiction of the government authority responsible for that food safety system, you, as the FSVP importer of food from the foreign supplier, are not required to: 1. Perform a hazard analysis, or 2. Conduct a foreign supplier evaluation for approval and verification.
PPT, PM	App. 5	Slide 22 A5-21	All	All	1	Moved previous slide 26 "FSVP When Food is from a Recognized System" and related text previously on page A5-21 to page A5-20. Changed title of slide 22 to "When Food Is Produced Under a Food Safety System Recognized by FDA (continued)" Changed the fourth sub-bullet under bullet 1 to say:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• Identify yourself as the FSVP importer named on the Customs & Border Protection (CBP) entry filing. Changed the second bullet to say: • Note: These provisions apply ONLY to food that is not intended for further manufacturing/processing before consumption. Deleted previous slides 27 & 28 “Foreign Supplier Must Be in ‘Good Standing’” and “Foreign Supplier Must Be in ‘Good Standing’ (continued)” respectively. Combined and changed the text from new slide 22 and previously deleted slides 27 & 28 (see note above) to say: You must, however, monitor whether the foreign supplier remains in good compliance standing with the foreign food safety authority, take prompt corrective action if any information indicates that the hazards associated with the food you import are not being significantly minimized or prevented, and ensure that you as the FSVP importer maintain records relative to all FSVP activities. You must also ensure that you are identified as the FSVP importer on the CBP entry filing and maintain records relative to all FSVP activities. Remember, whoever is identified on the CBP entry filing as the FSVP importer is the person FDA will see as being responsible for all FSVP activities, including the maintenance of all FSVP records. Note: This provision only applies to a food that is not intended for further manufacturing/processing before consumption, because if it is a food that is imported into the U.S. for further processing, the subsequent U.S. manufacturer/processor will likely need to comply with the PC rules (including regarding

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						supply-chain programs) as well as other U.S. food safety requirements. Before importing a food from the foreign supplier from a food safety system that has been officially recognized by FDA, you need to determine and document that the foreign supplier is in good compliance standing with the appropriate foreign food safety authority. Thereafter, you must continue to monitor whether the foreign supplier is in good compliance standing with the foreign food safety authority. Also, if you become aware of any information indicating that the hazards associated with the food you import are not being significantly minimized or prevented, you must take prompt corrective action.
PPT, PM	App. 5	Slide 23 A5-22	All	All	1	Moved previous slide 29 “Appendix 5: Summary” and related text previously on page A5-24 to page A5-22. Changed last bullet on slide to say: • Described the requirements when importing from a recognized food safety system. Changed the text beneath slide to say: We have described the modified requirements, identified a “very small importer” and “certain small foreign supplier,” discussed requirements if you are not a “very small importer,” but are importing from a “certain small foreign supplier,” and the requirements when importing from a recognized food safety system.
PPT, PM	App. 5	Slide 24 A5-22	All	All	2	Moved previous slide 30 “Appendix 5: Questions” previously on page A5-24 to page A5-22.
APPENDIX 6 CHANGES						
PM	App. 6a	A6a-2	PP 1	6 & 7		Corrected the name of the rule to say:

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						Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Food for Animals
PPT, PM	App. 6a	Slide 5 A6a-4			1	Changed the first bullet on slide to say: • Modernizes longstanding current CGMP requirements
PM	App. 6a	A6a-4 & A6a-5	All	All	2	Added the text "primarily in subpart B," after "…part 117," and before "and are shown…" in the first and second line of paragraph 1 beneath slide on A6a-4 and top of A6a-5. Added the text "(primarily in subpart B)" after "…21 CFR 117" and before "to clarify…" in the second line of paragraph 2. Changed the second sentence in paragraph 3 to say: Human food manufacturers that hold and distribute human food by-products without further manufacturing are not subject to the animal food rule if the human food facility is in compliance with CGMP and does not further manufacture or process the by-products intended for use as animal food, but the by-products must be held in a manner that protects against contamination. Added the text "(subpart A)" at the end of the last sentence, paragraph 4.
PPT, PM	App. 6a	Slide 7 A6a-6			1	Added the word "the" after "Does" and before "CGMP" in the slide title.
PM	App. 6a	A6a-7	PP 2	6	1	Changed the word "pre-requisite" to "prerequisite."
PM	App. 6a	A6a-8	PP 1 PP 4	8 4-6		Added the word "primarily" after "…requirements" and before "in subpart C…" in line 8 of paragraph 1. Changed sentence 2 in paragraph 4 to say: If a hazard does exist, and that hazard is controlled before receipt by a supplier, a written supply chain program, as described by subpart E of both rules, will be required.

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PM	App. 6a	A6a-10	PP 2	3-5		Changed the last sentence in paragraph 2 to say: The two regulations include a recall plan in the list of "preventive controls" to be consistent with the 2011 FDA FSMA language.
PM	App. 6a	A6a-11	PP 3	3-6		Changed the last sentence in paragraph 3 to say: The compliance date for written assurances was extended by two years for U.S. suppliers downstream to address feasibility concerns (see 81 Federal Register; August 24, 2016).
PPT, PM	App. 6a	Slide 14 A6a-13				Changed bullets 1 & 2 of the slide to say: • Generally needed in human food facilities handling foods with food allergens • Include procedures, practices, and processes that prevent cross-contact of allergens with foods not containing the allergen and mislabeling of product
PPT, PM	App. 6a	Slide 15 A6a-14				Changed bullet 1 of the slide to say: • Used to prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards
PPT, PM	App. 6a	Slide 16 A6a-15			1	Replaced the words "are best" to "have been" in the first bullet. Added asterisk to first sub-bullet, "Onside audits*" under the second bullet. Added footnote at the bottom of the slide that says: **An annual onsite audit is generally required when the hazard can cause Serious Adverse Health Consequences Or Death to Humans or Animals (SAHCODHA)*
PM	App. 6b	A6b-1	PP 1	1 & 2		Italicized the name of the Produce Safety rule in lines 1 & 2 in the first paragraph beneath slide, *"Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption"*

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
PPT, PM	App. 6b	Slide 4 A6b-2 & A6b-3	All	All	2	Changed slide 4 to say: Potential Routes of Contamination • Minimize hazards from: o Agricultural water o Domesticated and wild animals o Biological soil amendment of animal origin o Health and hygiene of workers o Equipment, tools, buildings, and sanitation o Growing, harvesting, packing, and holding activities Changed the text beneath slide to say: The Produce Safety rule, focuses on biological hazards and specifically defined hazard as any biological agent that has the potential to cause illness or injury in the absence of its control. FDA concluded that physical hazards that can cause injury and chemical hazards, such as from crop protection chemicals, rarely occur at levels that pose a risk of serious adverse health consequences or death for individuals that would consume the product, citing an analysis of scientific literature and recall data. Therefore, the rule focuses on potential microbiological hazards. FDA identified major routes of contamination on farms, and finalized requirements in certain areas, including agricultural water; domesticated and wild animals; biological soil amendments of animal origin; health and hygiene; equipment, tools, buildings, and sanitation; and growing, harvesting, packing, and holding activities. We'll cover these in more detail in the following slides.
PM	App. 6b	A6b-3	KP			Changed KP to say: Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces. If the water does not meet this definition, then the testing

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						requirements and additional items in Subpart E of the Produce Safety rule do not apply. For example, if a grower irrigates their lettuce using overhead irrigation from a pond, this would be considered agricultural water because it directly contacts covered produce. But, if a grower uses pond water to irrigate their apple orchard with drip irrigation and the water is not likely to contact covered produce, this application of water may NOT represent agricultural water.
PPT, PM	App. 6b	A6b-3 & A6b-4	PP 2-4	Multiple	1	Changed bullet 3 on slide to say: • Testing to demonstrate water used for certain purposes meets specific microbial criteria Changed bullet 2 and sub-bullet on slide to say (Note: sub-sub-bullets did not change): • During growing activities: o Microbial water quality profile Changed bullet 3 on slide to say (Note: sub-bullet did not change): • Certain activities (e.g., during and after harvest – washing, cooling): Changed paragraphs 2-4 beneath slide to say: If a farm chooses to treat the water, such as with a physical treatment or an antimicrobial pesticide product registered with the U.S. Environmental Protection Agency (EPA), the treatment method must be effective and consistently delivered and monitored in a manner to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria. Unless the agricultural water is treated or is provided by a public water supply that furnishes water that meets certain microbial requirements (e.g., no detectable generic E. coli per

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						100 mL), testing is required to demonstrate agricultural water meets specific microbial criteria. The farm must develop a microbial water quality profile of each water source used during growing activities. A microbial water quality profile consists of a geometric mean (GM) and a statistical threshold value (STV) of generic Escherichia coli (E. coli). For pre-harvest applications, each water source must have a GM of 126 CFU/100 mL or less and an STV of 410 CFU/100 mL or less generic E. coli. For during and after harvest activities, hand washing, or food contact surface applications, the water must have no detectable generic E. coli/100 mL.
PPT, PM	App. 6b	Slide 6 A6b-4	All	Multiple	1	Changed bullet 1 on slide to say: • Assess, as needed, relevant areas during growing for potential contamination from animals Changed the paragraph beneath slide to say: All domesticated and wild animals can be sources of human pathogens. When a reasonable probability that animals will contaminate covered produce in outdoor areas or partially enclosed buildings, farms are only required to assess, throughout the growing season, for potential contamination from animals. If significant evidence of potential contamination is found—such as animal excreta or crop destruction—the farm should evaluate whether the degree of animal contact makes it unwise to harvest some or all of the produce. Produce that is reasonably likely to be contaminated, such as with visible evidence of animal excreta, must not be harvested.
PPT, PM	App. 6b	Slide 7 A6b-5	All	Multiple	1	Changed the title of slide 7 to “Controlling Hazards from Biological Soil Amendments of Animal Origin (BSAAO)” Changed slide to say:

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						• Untreated human waste is not permitted • Requirements for untreated and treated BSAAOs • Application requirements are in the rule • Standards for processes to adequately treat BSAAOs are in the rule • No preharvest, application intervals for BSAAOs that are adequately treated (e.g., compost)—can apply at any time • Preharvest, application intervals for certain untreated or incompletely treated BSAAOs are being researched, to be published later • Untreated BSAAO may not be applied in a manner that contacts the harvestable portion of covered produce Changed the paragraph beneath slide to say: Just as animal excreta can be a source of human pathogens, so can Biological Soil Amendments of Animal Origin (BSAAO)and human waste. FDA determined that BSAAOs that do not contain manure or other animal material are less likely to contain human pathogens. BSAAOs that have been composted or otherwise treated in a manner to meet certain microbial standards can be applied to the soil at any time. These standards for processes to treat BSAAOs adequately as well as application requirements are in the rule. Human waste that has been treated in compliance with U.S. Environmental Protection Agency (EPA) regulations are permitted, but untreated human waste is not permitted during production of any covered produce. FDA originally proposed a preharvest interval for raw or incompletely treated BSAAOs applied in a certain manner, but determined that there is currently insufficient science to set a particular interval. Research is ongoing, and FDA intends to set a standard at a later date.

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
PPT, PM	App. 6b	Slide 8 A6b-6	All	Multiple	1	Changed slide to say: • Preventing contamination by ill or infected persons • Certain hygienic practices are required • Toilet and handwashing facilities must be adequate and readily accessible during covered activities • Farms must make visitors aware of policies and give them access to toilet and handwashing facilities • The rule specifies certain requirements for personnel qualifications, and o Harvesters and some supervisors receive additional training Changed paragraph beneath slide to say: Humans are a potential source of human pathogens, so health and hygiene practices, are important. Certain hygienic practices are required as well as certain measures to prevent those with applicable health conditions from contaminating covered produce and food contact surfaces (specified in Subpart D). Farms must have readily accessible toilet and handwashing facilities. These facilities should be adequately maintained and furnished whenever covered produce is being handled (Subpart L, Equipment, Tools, Buildings, and Sanitation). Not all carriers of pathogens will appear ill, so all workers who are reasonably likely to come in contact with produce or food contact surfaces must receive food safety training so that they know how they can avoid being a source of contamination. Harvesters and some supervisors must also receive additional training in recognizing and dealing with potential sources of contamination (Subpart C, Personnel Qualifications and Training). Farms must make visitors aware of policies and procedures to protect covered produce and food contact surfaces, and give them access to toilet and handwashing facilities.
PPT, PM	App. 6b	Slide 9	PP 1	Multiple	1	Added bullet 4 on slide to say:

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		A6b-7				• Pest control Changed the paragraph beneath slide to say: Equipment, tools, buildings, and other surfaces, can be harborages of human pathogens and potential sources of contamination. Equipment and tools must be designed and constructed to allow adequate cleaning and maintenance. Food contact surfaces of equipment and tools must be inspected, maintained, and cleaned, and sanitized when necessary and appropriate, to minimize the risk of contamination of covered produce. Buildings and other structures used in covered activities, such as to house food handling equipment or for produce handling or storage, must be of adequate size, design, and construction to facilitate maintenance and sanitary operations. Produce, food contact surfaces, and food-packing materials must be protected from contamination by pests in buildings. This means taking measures to exclude pests from fully-enclosed buildings, and taking measures to prevent pests from becoming established in partially-enclosed buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).
PPT, PM	App. 6b	Slide 10 A6b-8	PP 2 & 3	Multiple	1	Changed bullet 3 on slide to say: • Not distributing covered produce that drops to the ground before harvest (see rule for more details) Changed paragraphs 2 & 3 beneath slide to say: As mentioned earlier, harvesters must be trained to recognize covered produce that must not be harvested. There is also a requirement to identify and not harvest covered produce that is reasonably likely to be contaminated. Dropped covered produce must not be distributed (i.e. covered produce that drops to the ground before harvest); this does not apply to

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						root crops, crops that normally grow on ground (e.g., melons), or produce that is normally dropped to the ground during harvest (e.g., almonds). Food-packing and packaging material must be appropriate for its intended use. For example, must be packaged in a manner to prevent toxin production by Clostridium botulinum. Also, if food-packing materials are reused, steps must be taken to ensure that they are cleanable, do not support bacteria, and food-contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.
PPT, PM	App. 6b	Slide 12 A6b-9 & A6b-10	PP 1-3 & 6	Multiple	2	Added the word "Act" after "…FD&C" and before "still…" in sub-bullet under bullet 1 on slide. Changed sub-bullets 1, 3, & 4 under bullet 2 on slide to say (Note: sub-bullet 2 did not change): • Include prominently and conspicuously the name and the complete business address of the farm where the produce was grown on the food packaging label, on a poster, sign, or placard at the point of purchase, or on documents delivered with the produce; • Comply with the recordkeeping requirements (Subpart O) and Withdrawal of Qualified Exemption (Subpart R); and • Comply with the FD&C Act and ensure that the food offered for sale is not adulterated. Changed paragraphs beneath slide as note below: **PP 1, Line 4:** Added the words "the Federal" after "…subject to" and before "FD&C Act,…" **PP 2, Line 1:**

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						Added the words “are eligible for” after “Farms that” and before “a qualified exemption…” **PP 3, Line 3:** Added new last sentence of paragraph to say: Note: Keeping sales receipts is one way collect this information. **PP 6, Line 1:** Changed the beginning of the sentence to “qualified farm” with “Produce from a farm with a qualified exemption is still…”
PPT, PM	App. 6b	Slide 13 A6b-11	PP 1 & PP 3	1 & 3	1	Added the word “Act” after “…FD&C” & before “still applies…” in sub-bullet under bullet 2 on slide. Changed “Raw Agricultural Commodity (RAC)” to “RACs” in first line of paragraph 1 beneath slide. Deleted “(e.g., cooking)” after “…significance” and before “are also…” in third line of paragraph 3 beneath slide.
PPT, PM	App. 6b	Slide 14 A6b-12	PP 1	1 & 2	1	Changed bullet 1 on slide to say: • We have described the primary routes of contamination covered by the Produce Safety regulation. Changed line 1 & 2 in paragraph beneath slide to say: In this Appendix, we have identified the primary routes of contamination covered by the Produce Safety regulation,
APPENDIX 7 CHANGES						
PM	App. 7	A7-1				**Appendix 7 TOC:** Changed “Request for FSVP Records (Form 482d)” to “Request for FSVP Records (FDA Form 482d)” Changed “FSVP Observations (Form 483a)” to “FSVP Observations (FDA Form 483a)”

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						Deleted “Standards for Produce Safety Flowchart”
PM	App. 7	A7-3 to A7-8		3 & 4		Alphabetized resources within each resource category. Added “Chapter 1: Context” header **Added Chapter 1 Specific Resource:** Name of Resource: FSVP for Importers of Food for Humans and Animals • Location: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm • Purpose: Final rule for the Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals **Added 4 new Chapter 3 Specific Resources:** Name of Resource: Compliance Date Extensions and Clarifications for FSMA Final Rules • Location: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm517545.htm *Also located in your manual in Appendix 2 • Purpose: Summary of changes announced in the Final Rule Name of Resource: Compliance Dates for the Final Rule on FSVP for Importers of Food for Human and Animals* • Location: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm *Also located in your manual in Appendix 2 • Purpose: The compliance dates for importers subject to the Foreign Supplier Verification Programs (FSVP) rule Name of Resource: FSMA Inflation Adjusted Cut Offs

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						• Location: https://www.fda.gov/food/newsevents/constituentupdates/ucm553382.htm • Purpose: Several FSMA rules have provisions in which a value is adjusted for inflation and averaged over 3 years. We provide the values based on Price Deflators for Gross Domestic Product (GDP) and the average for the most recent 3 years starting with the base year 2011. Name of Resource: Information on Australia's Recognition with Links to the Evaluation Process • Location: https://www.fda.gov/food/newsevents/constituentupdates/ucm553382.htm • Purpose: FDA signed an arrangement with the Australian Department of Agriculture and Water Resources recognizing each other's food safety systems as comparable to each other. This is the third time that the FDA has recognized a foreign food safety system as comparable, the first being New Zealand in 2012 and Canada in 2016. Added new "PCPS: Preventive Controls and Produce Safety Session" header **Added 3 new PCPS Specific Resources:** Name of Resource: PC for Animal Food Rule • Location: https://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm • Purpose: Final rule for the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals Name of Resource: PC for Human Food Rule

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						• Location: https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm • Purpose: Final rule for the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Name of Resource: Produce Safety Rule • Location: https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm • Purpose: Final rule for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption **Added 1 new Chapter 4 Specific Resource:** Name of Resource: FDA Guidances Explain Certain Exemptions from FSMA* • Location: https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm569554.htm *Also located in your manual in Appendix 1 • Purpose: FDA has published three Guidance documents to help producers of food commodities covered by these earlier regulations understand which parts of the FSMA rules apply to them and how the FSMA rules may affect their operations. Added new Chapter 6: Foreign Supplier Verification" header **Added 2 new Chapter 6 Specific Resources:** Name of Resource: Compliance Date Extensions and Clarifications for FSMA Final Rules • Location: https://www.fda.gov/food/guidanceregulation/fsma/uc

Material Changed	Chapter	Slide/ Page # in V1.1	PP # IN, KP, RN, or EN	Line #	Slide Position on Page	Changes from V1.0 to V1.1
						m517545.htm *Also located in your manual in Appendix 2 • Purpose: This provides a summary of changes announced in the Final Rule: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules that impacts provisions in these four rules: Preventive Controls for Human Food, Preventive Controls for Food for Animals, Produce Safety, and Foreign Supplier Verification Programs (FSVP) Name of Resource: Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA • Location: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm524553.htm *Also located in your manual in Appendix 1 • Purpose: This guidance is intended for any entity that is subject to certain provisions (in part 117, part 507, the produce safety regulation, or the FSVP regulation) that require a disclosure statement, in documents accompanying food, that certain hazards have not been controlled by that entity. **Changed 1 Chapter 8 Specific Resource:** Name of Resource: Dun & Bradstreet – FDA DUNS Request web page • Location: http://www.dnb.com/government/duns-request.html • Purpose: To apply for a free DUNS number **Added 3 new Chapter 8 Specific Resources:** Name of Resource: FDA's Supplemental Guidance for the CBP and Trade Automated Interface Requirements

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						• Location: https://www.cbp.gov/sites/default/files/assets/documents/2017-Jan/FDA%20Supplemental%20Guide%20Release%202.5%20FINAL%20DEC%2028%202016%20.pdf • Purpose: To provide additional technical information on the CBP and trade automated interface requirements Name of Resource: Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the FSVP Regulation* • Location: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm *Also located in your manual in Appendix 1 • Purpose: Specifies FDA's current thinking on what unique facility identifier (UFI) FDA recognizes as acceptable for purposes of the Foreign Supplier Verification Programs (FSVP) regulation. Name of Resource: Guidance for Industry: Recognition of Acceptable Unique Facility (UFI) for the Foreign Supplier Verification Programs Regulation* • Location: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm *Also located in your manual in Appendix 1 • Purpose: Specifies FDA's current thinking on what unique facility identifier (UFI) FDA recognizes as acceptable for purposes of the Foreign Supplier Verification Programs (FSVP) regulation.
APPENDIX 8 CHANGES						
No Changes						
APPENDIX 9 CHANGES						

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PM	App. 9	A9-1				**Appendix 9 TOC:** Deleted the FSMA Final Rule on Foreign Supplier Verification Programs Fact Sheet from TOC and from Appendix 9.
PM	App. 9	A9-3 to A9-7				Replaced "Preventive Controls for Human Food Final Rule Fact Sheet" with "Preventive Controls for Human Food Final Rule Summary from FDA Website (for reference only)" from FDA's Website.
PM	App. 9	A9-9 to A9-14				Replaced "Preventive Controls for Animal Food Final Rule Fact Sheet" with "Preventive Controls for Animal Food Final Rule for Summary from FDA Website (for reference only)" from FDA's Website.
PM	App. 9	A9-15 to A9-24				Replaced "Produce Safety Final Rule Fact Sheet" with "Produce Safety Final Rule Summary from FDA Website (for reference only)" from FDA's Website.
PM	App. 9	A9-25 to A9-28				Replaced "Accredited Third-Party Certification Final Rule Fact Sheet" with "Accredited Third-Party Certification Final Rule Summary from FDA Website (for reference only)" from FDA's Website.
PM	App. 9	A9-29 to A9-33				Replaced "Final Guidance for Industry for FDA's Voluntary Qualified Importer Program (VQIP) Fact Sheet" with "Final Guidance for Industry for FDA's Voluntary Qualified Importer Program (VQIP) (for reference only)" from FDA's Website.
APPENDIX 10 CHANGES						
PM	App. 10	A10-8	KP			Changed the shape of the KP textbox to fit beneath "Preventive controls qualified individual" definition. Changed KP to say: Each of the Preventive Controls rules contains two definitions pertaining to "qualified individuals.' One definition, i.e., the "preventive controls qualified individual (PCQI)," focuses on the requirement that a PCQI must successfully complete

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						training under a standardized curriculum or have equivalent training to be considered a PCQI. The second definition in the PC rules, i.e., "qualified individual," is similar to the QI definition in the FSVP rule, in that a QI must have the education, training, or experience to carry out the tasks for which he/she is responsible. FSVP qualified individuals are not required to receive training under a standardized curriculum or equivalent training.
EXERCISE WORKBOOK CHANGES						
EW	TOC	1				Changed "Chapter 3: Overview of Requirements" to "Chapter 3: Overview of the Requirements" Changed "PCPS Session: Preventive Controls and Produce Safety Session" to "PCPS: Preventive Controls and Produce Safety Session" Changed "Chapter 7: Reevaluation of Foreign Supplier" to "Chapter 7: Reevaluation of Foreign Supplier Performance and Food Risk, and Corrective Actions" Changed "Chapter 8: Importer Identification" to "Chapter 8: Importer Identification at Entry"
EW	Ch. 2 Exercise	**3-6**				The following changes were made to scenarios: • Directions changed to say: Directions: In your group, read the scenarios and determine "Who is the FSVP importer?" (Scenarios #1-4) and both "Who is the FSVP importer?" and "Who is the foreign supplier?" (Scenarios #5a-5e). Report out to the instructor and class when called upon. Note: All company names and products are fictitious for the purpose of this exercise. • Scenario 2 description, last sentence was changed to say:

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						○ Paris Bakery ships the bread to fulfill the order. Paris Bakery actually owns the bread at the time of entry and is the importer of record; however, BreadCo has a written purchase agreement with Paris Bakery at the time of entry. • Scenario 3 description changed to say: • Retailer ABC, a U.S. company has a purchase order in place at the time of entry with Importer XYZ, a U.S. company, who has purchased candy from CandyCo, a British company, on behalf of Retailer ABC. Importer XYZ owns the product at the time of entry and is the importer of record. • Scenario 4 description, first sentence was changed to say: ○ A U.S. retailer works through an international importing firm who handles the procurement, shipment, and importation of foreign goods, including food, for its retail stores. • Scenario 5: Items 1-4 were relabeled to 5a to 5e. • Scenario 5c description changed to say: ○ U.S. entity has agreed to purchase fresh, whole tomatoes imported by a U.S. consolidator who does not own the tomatoes at the time of entry. • Scenario 5e description changed to say: ○ U.S. entity has agreed to purchase fresh, whole tomatoes imported by a U.S. consolidator who sources the tomatoes from Mexico and owns them at time of entry.
EW	Ch. 3 Exercises	7-10				Changed the “NO” answer on slide and in the text below to say: • NO: FSVP does not apply to you for this food.

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						Changed "YES" answer on slide and in the text below to say: • YES: FSVP does not apply to you for this food. Changed the question to say: • Are you an importer subject to the preventive controls regulation for human or animal food, a food processor/manufacturer receiving the imported food, and in compliance with one of the following requirements in 21 CFR parts 117 or 507? o You implement preventive controls for the hazards in the food in accordance with either of the Preventive Controls rules; o (2) You are not required to implement a preventive control under either of the preventive controls rules; or o (3) You have established and implemented a risk-based supply-chain program in compliance with either of the preventive controls rules. Changed the question to say: • Do you import a food that is not intended for further manufacturing/processing before consumption from a country that is officially recognized by FDA as having a food safety system that is comparable for certain foods under Systems Recognition? (See 21 CFR 1.513)? Changed the "YES" answer to say: • YES: You may be subject to modified FSVP requirements for food from those countries if the food is under the regulatory oversight of the food safety authority, the food is within the scope of the recognition agreement, and the supplier is in good

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						compliance standing with the relevant food safety authority in that country. Changed the "YES" answer to be consistent with slide changes: • YES: You may be subject to modified FSVP requirements for food from those countries if the food is under the regulatory oversight of the food safety authority, the food is within the scope of the recognition agreement, and the supplier is in good compliance standing with the relevant food safety authority(ies) in that country. Changed the "Does FSVP apply to these food products?" exercise directions to say: • Directions: In your group, read the example food products listed in the table. Discuss whether the FSVP standard requirements apply, the modified requirements apply, or if the food is exempt. The instructor will call upon each group to put their answers on the projector screen using post-it notes. Be sure to identify your group as suggested by the instructor. Changed food products as follows: Bottled maple syrup ready for retail sale, product of Canada Tomatoes from Mexico sold to a U.S. canner
EW	Ch. 4 Exercise	12-14				Changed the exercise "Identify "Known or Reasonably Foreseeable" Hazards" directions to say: Directions: 1. Review the example (on page 34 in the Participant Manual and below). 2. The instructor will use two or three examples of food products imported by participants for the

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						exercise (or the instructor will provide an example). 3. The instructor or the person(s) who provided the examples, will describe the process each example food product goes through to be sure everyone has an understanding of the potential hazards. 4. The instructor will walk the participants through the activity of identifying any "known or reasonably foreseeable" biological, chemical, and physical hazards for each example food product. ***Note:*** *This exercise is NOT a hazard analysis; it is only one step within the hazard analysis. The goal of the exercise is to identify "known or reasonably foreseeable" hazards.* Added an "Example for Review" table using the "Pumpkin seeds" example previously on table, including the answers. Added 3 blank tables for "Example Ingredient/Food Product 1, 2, and 3, if needed.
EW	Ch. 5 Exercise	15				Changed name of exercise to "Group Exercise: Who Is Controlling the Biological Hazards?" Added a note at the top of the exercise that says: ***Note:*** *For this exercise, we are only considering biological hazards, even though the hazard analysis must also include analyses for physical and chemical hazards. Also note that the purpose of this exercise is to consider who is controlling the hazards and not, specifically, who is the foreign supplier. Under the FSVP rule, there is only one foreign supplier but there may be several entities that control the hazards. While an importer must only verify one foreign supplier, they must still consider all entities that control the identified hazards (scenarios are on the next slide).*

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EW	Ch. 6 Exercise	16				Deleted previous Scenario 1; changed “Scenario 2” to “Scenario”
EW	Ch. 7 Exercise	17				Changed the group exercise directions to say: **Directions:** The Instructor will review a few of the examples and ask if anyone can think of any other issues that could trigger a reevaluation. Be prepared to offer an example. Also, be prepared to identify why each of these examples issues would trigger a reevaluation. Discuss as a group.
EW	Ch. 8 Exercise	18				Changed exercise name to “Group Exercise: Importer Designation at Entry” Changed scenario 1 header to say: Scenario 1: A U.S. retailer regularly uses a multinational produce distributor (who has offices in the U.S.) to buy pineapples. Changed scenario 2 header to say: Scenario 2: The distributor in Scenario 1, has heard about, but does not wish to deal with, the FSVP requirements for the pineapple shipments.
EW	Ch. 9 Exercise	19 & 20				Changed question 2 to say: If an importer relies on the hazard analysis of another entity, the importer must keep records of its review and assessment of the hazard analysis. Changed question 3 to say: If an importer reviews and assesses the foreign supplier’s hazard analysis, the importer must keep a record that the supplier’s hazard analysis was conducted by a qualified individual. Corrected question 4 to say:

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						FSVP importers must have written procedures for 1) ensuring that foods are imported only from approved foreign suppliers, and 2) ensuring that appropriate foreign supplier verification activities are conducted for the foods you import. Changed question 5 to say: Importers must reevaluate their FSVP (i.e., specifically their foreign supplier's food safety performance and risk posed by the food) promptly, if a problem or change occurs that could impact food safety, but at least every year. Changed question 7 to say: An FSVP importer who uses audits to verify their supplier's compliance with FDA food safety standards must retain copies of the full audit reports in their records. Changed question 9 to say: Importers' FSVP records must be signed and dated upon initial completion and any subsequent modification.