

Below you will find changes made to the FSPCA Preventive Controls for Human Food course: Versions 1.0 and 1.1. Those with **Version 1.0** will need to address all changes within their materials. Those with **Version 1.1** will only need to address changes identified as Version 1.1.

Abbreviations for materials: *PM = Participant Manual, EW = Exercise Workbook*

Material Changed	Version	Page #	Paragraph # Text Box Inst. Note	Line #	Slide Position on Page	Changes
PM	1.1	Front Cover				Changed date on front cover to 2016.
PM	1.1	Title Page				Changed date to 2016 and add "Version 1.2, February 2016)" to identify manual version
PM	1.1	Preface ii				Added text to about version 1.2 "Version 1.2 contains changes to address technical amendments and corrections published by FDA, and editorial corrections identified in earlier versions. An erratum listing for earlier versions is available on the FSPCA website."
PM	1.1	Preface iv				Moved "Any individual, company, agency or nation can provide input for the FSPCA program through communications with any member of the FSPCA Steering Committee. Participation in working groups is also possible." to the end of the paragraph. Also added participation in "sub-committees" in addition to working groups, and added "Visit the FSPCA website for information on active sub-committees and working groups."
PM	1.1	Preface iv	2			Added underlined text "FSPCA <u>Preventive Controls for Human Food course</u> "
PM	1.1	Preface iv	3			Added underlined text "FSPCA <u>Preventive Controls for Human Food course</u> "
PM	1.1	1-1	1	1	1	First slide now says "preventive controls qualified individual"
PM	1.1	1-3			2	Removed asterisk next to the space program
PM	1.0	1-3			2	Removed asterisk next to the milk

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PM	1.1	1-7	1	1		Added words in parenthesis "... certain tasks must be performed (or overseen) by a..."
PM	1.1	1-10				Changed the definition of "Cross-contamination: The unintentional transfer of a foodborne pathogen from a food (where it may occur naturally) or insanitary object to another food (where it may present a hazard)."
PM	1.1	1-10	1	1		Changed "a supplier's" to "an entity's" to address technical amendments published 22 January 2016
PM	1.0	1-11	Text Box			Added "Very small businesses and businesses..." to the beginning of this bullet
PM	1.1	1-14				Inserted in the alphabetical listing (before SOP): "Small business3: A business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees."
PM	1.1	1-16				Formatting and spacing corrections.
PM	1.1	2-3	1		1	On slide, under botulism example, after "customers" changed to "Supply-chain program"
PM	1.0	3-1	3	3		Removed parenthesis from "Plan and (in some cases..."
PM	1.1	3-3			1	Training slide bullet 3 now reads, "...appropriate knowledge..."
PM	1.0	3-10	3	5		Changed "must" to "should"
PM	1.0	3-10			1	Changed major bullet #2, deleted "and stocked with supplies"
PM	1.0	3-12		4		Changed "take all reasonable" to "take adequate..."
PM	1.1	3-12			1	Changed "Adequate" to "Appropriate..."
PM	1.1	3-12			2	4th major bullet now reads "Prevent allergen cross-contact..."
PM	1.0	3-13	1	5		Deleted "and the carriers that bring them to the facility"

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	1.0					
PM	1.1	3-15			1	Slide change Bullet 3 - Delete "other".
PM	1.0	3-18	3			Deleted the sentence "A supply-chain program...manufacturing or processing."
PM	1.0	3-19			2	Last bullet - deleted "additional"
PM	1.1	4-2			1	Bullet 2 now reads "Undesirable conditions that generally are not hazards requiring a preventive controls, e.g.:"
PM	1.1	4-3			1	Changed "Use are" to "Use is."
PM	1.1	4-8	Text box Line 3			Changed "FDA's Dairy Hazard Guide" to "FDA's Dairy Hazards Guide" Formatting and spacing corrections
PM	1.1	4-10	Text box			Changed "In the graph:" to "For example,"
PM	1.1	4-21			1	Changed to "Prerequisite programs," to "GMPs,"
PM	1.1	5-2			1	Changed "PC" to "preventive control"
PM	1.0	5-2			1	Deleted slide bullet 2 - "not related to food safety" replaced with "that generally are not hazards requiring a PC"
PM	1.0	5-5			1	Used slide on 4-3 w/updated data but used only one bullet that reads "Undeclared allergens represent about 1/3 of RFR reports."
PM	1.1	5-8			1	Changed "Clostidium" to "Clostridium"
PM	1.0	5-16	2	1		Added "...legally used." [deleted "including limiting use... may be considered unsafe in others."]
PM	1.0	5-22	1	11		Changed "IRAC" to "IARC"

Material Changed	Version	Page #	Paragraph # Text Box Inst. Note	Line #	Slide Position on Page	Changes
PM	1.1	6-5	3	3		Made the reference to "Table 6.1" consistent to the format on page 6-8 by doing the following: 1) Cut the first sentence of paragraph 2 under the slide and paste it into a new participant text box and modify it to read "Elements of the product description and distribution, as well as the information on consumers and intended use (discussed in the next section) are listed in a table on page 6-8." 2) Combine the remaining sentence from paragraph with the first paragraph under the slide, i.e., "of bacteria. It is important to understand..."
PM	1.1	6-14	1	3		Deleted "Available at" from the reference
PM	1.1	6-14	Table	"Directions"		Focus shifted to the objective – "to become familiar with the product." Added to the "Directions" box above the numbered list: "Emphasize that the primary objective of this exercise is to become familiar with the product that they will be working on in subsequent exercises."
PM	1.1	7-3				Formatting and spacing corrections.
PM	1.0	7-3	Text Box			Deleted text box
PM	1.0	7-3	2	10		Added new sentence at end of the paragraph – "The FSPCA Technical Assistance Network is discussed in the upcoming section on Reliable Internet Sites."
PM	1.0	7-3	4	5		Deleted "For example, FDA's web forum provides information at www.fda.gov/fsma . Other agencies may provide fee for service offerings." Added "See the discussion in Reliable Internet Sites"
PM	1.0	7-6			1	Added the new slide on the Technical Assistance Network to the deck and insert it before the heading "Food Safety Preventive Controls Alliance (FSPCA) Website"
PM	1.1	7-6			1	Inserted the new slide with "web form" instead of "email" for the FSPCA.

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PM	1.0	7-6	Text Box			Moved paragraph 3 to text box on the side. "FDA's FSMA Technical Assistance Network, which provides answers to policy interpretation questions"
PM	1.0	8-1			1	Removed "s" from controls on slide
PM	1.1	8-4			2	Changed "supercedes" to "supersedes" in sample document.
PM	1.1	8-9			1	Changed title of slide from "Hazard Identification Considerations" to "Hazard Evaluation Considerations".
PM	1.1	8-11	All			Moved all content from page 8-11 to page 8-9 and moved all content from pgs. 8-9 - 8-10 to after the new content on 8-9. Moved slide 14 to slide 13 in PPT to reflect new order of content.
PM	1.1	8-22			1	Modified table: column 3 - deleted "are significant" and added "require a preventive control"; Column 5 - Deleted "Significant." Changed to "For hazards requiring a preventive control ("Yes" in column 3 ...).
PM	1.0	8-23			1	The table is updated. Everything in row "P" was moved to row "C". The word "None" was moved to row "P: column "2"
PM	1.1	8-23				Updated date of version for hazard analysis to reflect change in date for A3 modifications. Other slides with this information were also changed.
PM	1.1	8-26			2	Corrected spelling of "Cartons" on second slide, column 4, row 2.
PM	1.1	8-28			1	Changed columns 5 & 6 on slide to match Omelet example: 5 "Supply-chain Control - approved supplier and 3rd party supplier audit by a qualified auditor" Added 6-X in "Yes" column.
PM	1.1	8			Slides 27-35 in PPT	<i>Slides not in book.</i> Changed issue date from 09/21/2015 to 09/20/2015 to be consistent with header in Ap3.
PM	1.1	9-4			1	Replaced "From 21 CFR..." to "Derived from 21 CFR..." which is consistent with the footnote used in Chapter 1.

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PM	1.1	9-9				Moved operating limit discussion before monitoring and corrective action. The slide on operating limits includes a graphic with monitoring and corrective action implications, which is why it is on 9-27. Added an instructor's note on page 9-9 next to slide "Operating limits are discussed after monitoring and corrective action concepts are addressed."
PM	1.0	9-17			1	Spelled out "quality assurance"
PM	1.1	9-18	Text Box			Text now reads: "Monitoring personnel (qualified individuals) are not required to be "preventive controls qualified individuals" but must receive the food safety training required by regulation and be trained to perform their assigned task."
PM	1.1	9-19			1	Changed wording in the omelet plan for consistency. In Frequency column, inserted "about" before "every" to read: "Each cook station, 4 times per shift, about every 2-3 hours".
PM	1.1	10-2	2	3		Deleted "a" in "1) allergen labeling at <u>a</u> other steps and"
PM	1.1	10-2	Text Box			Added participant box stating "The term "sanitation" may include both cleaning and sanitizing activities. Cleaning is necessary to control allergens. Sanitizing, which is intended to kill microorganisms, has little or no impact on allergens."
PM	1.1	10-8			2	Deleted "full" from the bottom of the slide and from appendix A3, pg 20. Made change to Appendix 3, pg 20 as well.
PM	1.1	10-17			2	Added new last sub-bullet "Manage formula changes to ensure that the correct label is used during transition".
PM	1.1	10-21	Text box			Added to the text box below Slide 1 "Training may be appropriate for a label developer, for example if a mistake is made on the copy sent to the printer."

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PM	1.1	10-21	Text box			Created new participant text box "Label review could be done only at the labeling step, but many organizations perform two label reviews 1) upon receipt and 2) at labeling step. Complex labels require careful review by people trained in technical label wording requirements. Application of the label on line may be simply matching a label number to the product formula."
PM	1.1	10-23	Text box			Added "(21 CFR 117.3)" to Definition box
PM	1.1	10-26				In the "Direction" box, sentence after the bullets, added the following in bold; "Refer the class to the omelet example, which provides examples and information on using the forms."
PM	1.1	11-1	Text Box			Changed the definition of "Cross-contamination: The unintentional transfer of a foodborne pathogen from a food (where it may occur naturally) or insanitary object to another food (where it may present a hazard).
PM	1.1	11-1	Text Box			Text Box – deleted "ready-to-eat"
PM	1.0	11-6	1	6		Changed "manufacturing of" to "manufacturing"
PM	1.1	11-9			1	Removed cross hatch area in slide
PM	1.1	11-11			2	Slide 2 - "Sanitation Monitoring" first sub-bullet of bullet #1 - Changed "CFR 21: 117.3" to "21 CFR 117.3".
PM	1.1	11-12			1	Fixed to match Food Safety Plan in appendix i.e. footnote for "NA" - add the word "Biscuit" after "Omelet"
PM	1.1	11-13		1		Above Slide 1, Changed "The date, time and, when appropriate, initials of the operator..." to "The date, time (when appropriate), and initials of the operator..."
PM	1.1	11-13	Text box			Added bold words below in second text box to read: "...cross-contact must be taken in a timely manner." And "If action is not taken in a timely manner..."

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PM	1.1	11-14			1	Removed dates from slide to avoid future update
PM	1.1	12-1			1	Updated the corrected PPT slide image in the books – now contains the correction (i.e., "linked to hazard analysis".)
PM	1.0	12-1			1	Added to bullet 1 – "...are linked to the hazard analysis"
PM	1.1	12-4	Text Box			Add participant text box stating: "While the 3rd party audit is not conducted at receiving, the shipping clerk checks to assure that the material came from the approved supplier. Because the audit is not conducted at receiving then others may choose to check no."
PM	1.1	12-9	1	4		Changed to "see verification discussion below")"
PM	1.1	12-11	1		1	The following was added as well as a new bullet on the summary slide. "A Recall Plan is required when hazard analysis identifies a hazard requiring a preventive control, and it is a good idea to have one even if you do not identify such a hazard."
PM	1.0	12-12			1	Slide title changed "exemptions" to "exceptions"
PM	1.0	12-19			1	Slide and margin – removed random dots
PM	1.1	12-21			1	Changed "take" to "taken" on slide.
PM	1.1	13-1		12		Changed line 12 to now read "A preventive controls qualified individual must perform or oversee <u>validation and most</u> verification activities."
PM	1.1	13-2			2	Removed sub bullet "Record Review" from under Process Verification bullet and added "In addition to records review for all preventive controls:" as a heading at the top of the slide.
PM	1.0	13-3			1	Matched the slide to the book. Should be "preventive controls qualified individual" instead of just "qualified individual"

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PM	1.1	13-8			1	Bullet 2 changed to "Required as appropriate to the food, facility, and nature of the preventive control"
PM	1.1	13-8			1	1st sub-bullet - added "and verification" to the phase to read "Calibration of process monitoring and verification instruments"
PM	1.1	13-9			2	Under pH heading, in "Calibration" column, changed "or" to "of"
PM	1.1	13-10			2	Deleted last bullet on slide, "What is being measured and for what purpose are the data used"
PM	1.1	13-12			1	Added a "Records should:" bullet and moved the "Provide a traceability to a reference device" sub bullet to under the "Records should:" bullet
PM	1.1	14-6	Text box			Added a text box next to slide 1 stating "A Food Safety Plan cover sheet that is signed and dated by the responsible individual is sufficient"
PM	1.1	14-6			2	Slide content changed: 3rd bullet - changed to "date and, when appropriate, time of activity documented.", title - removed "All", 4th bullet - added ", as applicable" to end of phrase. Formatting adjustments to slide.
PM	1.1	14-8			1	Deleted from last bullet "trained".
PM	1.1	14-9			2	Changed slide in the "back of chart" side to "2/3 - 2/9/ 2014".
PM	1.1	14-11			1	Changed slide title from "correction" to "corrective".
PM	1.1	14-16			2	Changed Column headings for the Reanalysis Checklist to: 1) Task, 2) Date Reviewed and Initials, 3) Is Update Needed? (yes/no), 4) Date Task Completed, 5) Signature or Initials of Person Completing the Task. [Column 2 is new]. Added the updated table to Appendix 2.
PM	1.1	14-16	Text Box			Inserted text box next to slide: "This form is not required but may be a useful starting point. Reanalysis must be documented as discussed in the verification chapter."

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PM	1.1	14-19			1	Corrected verbiage on last bullet, the 2nd word now reads "and"
PM	1.1	15-9			1	Formatting adjustments to PPT.
PM	1.1	15-22				Changed in Table 1, line 1 - "Rational" to "Rationale"
PM	1.1	15-23				Added even page numbers to the bottom of the page for the recall plan.
PM	1.0	16-4			2	Added to sub bullet 1: "human food plus value of food held without sale"
PM	1.0	16-5			1	Deleted last bullet "raw agri products"
PM	1.0	16-5			1	Deleted "raw agricultural commodities"
PM	1.0	16-6			1	1 st sub bullet, added citation at end "(117.206)"
PM	1.0	16-6			2	Changed citation to (117.5(j))
PM	1.0	16-7	2	1		Added the following text to the beginning of the paragraph: "21 CFR 117 Subpart B (GMPs) does not apply to farms and activities of farm mixed-type facility, fishing vessels, establishments solely engaged in holding or transportation of RACs, and establishments solely engaged in hulling, shelling..." retained the remainder of the paragraph
PM	1.0	16-7				Added citation "(117.5(g)(h))"
PM	1.0	16-13			1	Deleted slide
PM	1.1	A1-1	Title			Deleted "(FSMA Section 103)"
PM	1.1	A1-all				Technical amendments and corrections to the final rule were published January 22. Use FSPCA Ap1 Reg 2016 01 25 AMENDED.docx in place of previous version
PM	1.1	A2-6				Changed "Parameter" to "Criterion"

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PM	1.1	A2-12				Added example of corrective action form to provide even number of pages
PM	1.1	A3-19				Formatting adjustments to table
PM	1.1	A4-2				Changed <i>C. perfringens</i> maximum water activity to ">0.99." Updated PPT.