

## MEMORANDUM

**From:** Joseph A. Levitt  
Elizabeth Barr Fawell  
Maile Gradison Hermida

**Date:** November 30, 2018

**Re: Intentional Adulteration Rule under FSMA Training Requirements and Course Availability**

This week, the Food Safety Preventative Controls Alliance (FSPCA) released the online course “Conducting Vulnerability Assessments Using Key Activity Types” (KAT Course).<sup>1/</sup> This course satisfies the training requirement in the Mitigation Strategies to Protect Food Against Intentional Adulteration final rule (IA rule) to conduct a vulnerability assessment if using the Key Activity Types method. Below, we review the requirements for “qualified individuals” in the IA rule and provide additional details on the training courses available now and forthcoming from FSPCA.

### Overview of Qualified Individual Requirements for the IA Rule

FDA issued the final IA rule in May 2016, establishing for the first time the requirement for covered facilities to develop and implement food defense plans. When preparing a food defense plan, the IA rule requires facilities to conduct a vulnerability assessment, identify and implement mitigation strategies, and then oversee the implementation of those mitigation strategies through monitoring, verification, corrective action, and recordkeeping activities. Among other things, the IA rule requires “qualified individuals” to perform food defense tasks under the rule. A “qualified individual means a person who has the education, training, or job experience (or a combination thereof) necessary to perform an activity . . . , as appropriate to the individual’s assigned duties.”<sup>2/</sup> The qualification requirements are as follows:

- Individuals Assigned to Actionable Process Steps (and their supervisors)
  - Must be a “qualified individual” and have the education, training, and/or experience necessary to properly implement the mitigation strategy at the actionable process step
  - Must receive training in food defense awareness

---

<sup>1/</sup> This course and others can be found here: <https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration>. This website contains course descriptions and other course information.

<sup>2/</sup> 21 C.F.R. § 121.3.

- Individuals Who Do or Oversee the Preparation of the Food Defense Plan; the Vulnerability Assessment; the Identification and Explanation of Mitigation Strategies; and the Reanalysis of the Plan
  - Must be a “qualified individual”
  - Must have successfully completed training for the specific activity at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities <sup>3/</sup>
- Supervisors Assigned to Ensure Compliance with the Rule
  - Must have a combination of education, training, and experience necessary to supervise activities under the rule

Although the IA rule does not expressly refer to individuals who do or oversee the preparation of the food defense plan and related specialized activities as “Food Defense Qualified Individuals,” the requirements for these individuals parallel those found in the Preventive Controls rules for “Preventive Controls Qualified Individuals” (PCQIs). A qualified individual may be, but is not required to be, an employee of the establishment.

### Summary of Qualification Requirements and Relevant FSPCA IA Training Courses

The FSPCA has several courses available to assist industry in compliance with the IA rule’s qualified individual requirements and additional courses are forthcoming. The training courses developed by the FSPCA are the “standardized curriculum” recognized by FDA and are one way to meet the qualification requirements in the rule. The attached course schedule from FSPCA provides a summary of the IA rule training courses. The following table is a summary of both the qualification requirements in the IA rule and the FSPCA training courses.

Who			Qualification Requirements	FSPCA Course
Individuals assigned to actionable process steps and their supervisors			Must be a “qualified individual” and have the education, training, and/or experience necessary to properly implement the mitigation strategy at the actionable process step (§ 121.4)(b)(1))	N/A (on the job training)
			Must receive training in food defense awareness (§ 121.4)(b)(2))	<i>Food Defense Awareness</i> course - Currently available online - Free of charge
Individuals who	Conduct the vulnerability	Using the KAT method	Must be a “qualified individual” (§ 121.4(c)(1))	<i>Conducting Vulnerability Assessments Using the Key Activity Type Method</i> course

<sup>3/</sup> To qualify through “job experience,” the individual must have “knowledge at least equivalent to that provided through the standardized curriculum.” 21 C.F.R. § 121.4(c)(2).

	assessment		<p>Must have successfully completed training for the specific activity at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities (§ 121.4(c)(2))</p>	<ul style="list-style-type: none"> <li>- Currently available online</li> <li>- \$159</li> <li>- Is strongly recommended before taking the <i>Conducting Vulnerability Assessments</i> course</li> </ul>
		Using the 3 fundamental elements in the regulations <u>4/</u>		<p><i>Conducting Vulnerability Assessments</i> course</p> <ul style="list-style-type: none"> <li>- Must be taught by an FSPCA Lead Instructor</li> <li>- One-day in-person training</li> <li>- Forthcoming in February</li> <li>- Cost will be set by Lead Instructors</li> </ul>
		Identify and explain mitigation strategies		<p><i>Identification and Explanation of Mitigation Strategies</i> course</p> <ul style="list-style-type: none"> <li>- Will be available online in January</li> <li>- \$169</li> </ul>
		Prepare the Food Defense Plan		<p><i>Food Defense Plan Preparation and Reanalysis</i> course</p> <ul style="list-style-type: none"> <li>- Will be available online spring 2019</li> <li>- Cost is TBD</li> </ul>
	Conduct Reanalysis			
Supervisors assigned to ensure compliance with the rule			<p>Must have a combination of education, training, and experience necessary to supervise activities under the rule (§ 121.4(d))</p>	N/A

Training for workers at actionable process steps may require facility specific information for proper implementation of the mitigation strategy or strategies and, therefore, will need to be developed and administered on the job and will not be developed by FDA.



\* \* \*





We will continue to monitor developments on FDA's implementation of the IA rule and the availability of guidance and training materials. Please contact us if you have any questions.

---

4/ Individuals can conduct a vulnerability assessment using ONLY the KAT method and if they do so, do not need to take the *Conducting Vulnerability Assessments* course that explains how to use the three fundamental elements in the regulations. However, if you want to deviate from the KAT method you will need to take the *Conducting Vulnerability Assessments* course, or be otherwise qualified through job experience to conduct the vulnerability assessment.

Course descriptions, information packets and registration links found on the FSPCA website at <https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration>

FSPCA IA Rule Training Courses	Delivery Method	Intended Audience	Cost
<b>Food Defense Awareness</b>	Available now 	<ul style="list-style-type: none"> <li>Workers at Actionable Process Steps (e.g., front line food workers)</li> <li>Supervisors of Workers at Actionable Process Steps</li> <li>Satisfies requirement in § 121.4(b)(2)</li> </ul>	Free
<b>Overview of IA Rule</b>	Available now 	<ul style="list-style-type: none"> <li>Any stakeholder interested in learning more about the IA rule requirements</li> <li>This course is not associated with any IA rule training requirement</li> </ul>	Free

FSPCA IA Rule Standardized Curriculum Recognized by FDA*	Delivery Method	Intended Audience	Cost
<b>Conducting Vulnerability Assessments using Key Activity Types</b>	Available now 	<ul style="list-style-type: none"> <li>Food professionals who conduct VAs using the KAT Method only</li> <li>This course is strongly recommended before taking the Conducting Vulnerability Assessments course</li> </ul>	\$159.00 USD
<b>Identification and Explanation of Mitigation Strategies</b>	Available January 2019 	<ul style="list-style-type: none"> <li>Food professionals who identify Mitigation Strategies to implement at Actionable Process Steps</li> </ul>	\$169.00 USD
<b>Conducting Vulnerability Assessments</b>	Available February 2019  1-Day Course	<ul style="list-style-type: none"> <li>Food professionals who conduct VAs using the 3 Fundamental Elements</li> <li>This 1-day course must be taught by FSPCA VA Lead Instructors</li> <li>The VA/KATs online course is strongly recommended before taking this course</li> </ul>	Varies – price set by independent VA Lead Instructors
<b>Food Defense Plan Preparation and Reanalysis</b>	Available Spring 2019 	<ul style="list-style-type: none"> <li>Food professionals who prepare the Food Defense Plan and/or who conduct Reanalysis activities</li> </ul>	\$TBD

\*These courses satisfy the training requirements in § 121.4 of the IA Rule