

Assisting Food Processors with Food Safety Modernization Act Compliance

Abstract

The Food Safety Modernization Act (FSMA) Human Food Audit Checklist was developed as a tool for assisting food processors with implementation of FSMA. This 70-page checklist incorporates Title 21 Code of Federal Regulations (CFR) Part 1 Subparts H (Registration of Food Facilities) and O (Sanitary Transportation of Human and Animal Food) and 21 CFR 117 (Preventive Controls for Human Food Hazard Analysis and Risk-Based Preventive Controls and Current Good Manufacturing Practices) with hints, comments, and definitions. The checklist was reviewed by Food and Drug Administration experts and food company personnel to validate its usefulness. It can be modified to fit any food processor or regulation.

Keywords: [checklist](#), [Preventive Controls](#), [Food Safety Modernization Act](#), [food safety](#), [food safety education](#)

Jacques L. A. Overdiep III
Graduate Student
overdiep@iastate.edu

Angela M. Shaw
Associate Professor,
Extension and
Outreach
angelaml@iastate.edu

Department of Food
Science and Human
Nutrition
Iowa State University
Ames, Iowa

Introduction

Implementation of the Food Safety Modernization Act (FSMA) has caused concern among food facility operators due to the number of associated regulations and the complexity of the act's legal language. FSMA is a set of regulations established by the U.S. Food and Drug Administration to improve the production, processing, and handling of food in the United States. Many operators without prior exposure to food safety management systems and standards, such as Hazard Analysis and Critical Control Points, are lagging behind in understanding how to apply the FSMA rule. This circumstance has resulted in companies needing assistance with the transition to compliance (Grover, Chopra, & Mosher, 2016; Levin & Newslow, 2013). Grover et al. (2016) found that one of the most important factors for successful adoption of FSMA was understanding the law.

Researchers in the north-central region of the United States conducted a needs assessment based on the FSMA Produce Safety Rule. Results revealed that food industry members desired checklists as a preferred method of information delivery (Strohbehn et al., 2018). Checklists have proved incredibly useful in the military, medical, and extension fields (Gawande, 2007; Giampaoli, Cluskey, & Sneed, 2002; Haynes et al., 2009; Reed & Schuster, 2002; Shaw, Strohbehn, Naeve, Domoto, & Wilson, 2015). Within the food safety discipline, checklists have been used by grocery stores for verifying practices used by produce growers (Shaw et al., 2015). Prior to the project described herein, no checklist had been developed for assisting food manufacturers with FSMA education. To assist food manufacturers in complying with the FSMA rule, Iowa State University developed a checklist of 70-plus pages titled "FSMA Human Food Audit Checklist." This tool, which we introduce here, provides users with a

better understanding of the Current Good Manufacturing Practices, Preventive Controls for Human Food, Sanitary Transportation, and Amendments to Registration of Food Facilities aspects of the FSMA rule. The modifiable checklist is available for use by anyone in the food industry at

https://www.ncrfsma.org/files/page/files/humanfoodsafety_for_processors_update_12_19_17.pdf.

Methods

Content of Checklist

The checklist was developed directly from the FSMA regulations, Title 21 Code of Federal Regulations (CFR) Part 1 Subparts H (Registration of Food Facilities) and O (Sanitary Transportation of Human and Animal Food) and 21 CFR 117 (Preventive Controls for Human Food Hazard Analysis and Risk-Based Preventive Controls and Current Good Manufacturing Practices). The tool is actually made up of four distinct checklists, each with its own parts. The Hazard Analysis and Risk-Based Preventive Controls checklist contains 12 parts, the Current Good Manufacturing Practices checklist contains 10 parts, the Sanitary Transportation of Human and Animal Foods checklist contains 10 parts, and the Registration of Food Facilities checklist contains eight parts (Figure 1). Each part of a checklist is between one and three pages, and the content refers directly to the applicable section in the law and includes an accompanying hint that provides additional details of use to the checklist user. At the end of each part of a checklist, comments and definitions from the relevant rule (21 CFR §1.227, §1.904, or §117.3) are provided. Figure 2 provides an example of this format.

Figure 1.

Table of Contents of the Food Safety Modernization Act Human Food Audit Checklist

Hazard Analysis and Risk-Based Preventive Controls:

- 1) Preventive Controls Qualified Individual – §117.180(c)(1)
- 2) Contents of a Food Safety Plan – §117.126
- 3) Hazard Analysis – §117.130
- 4) Preventive Controls for Hazards – §117.135
- 5) When Preventive Controls are not Required – §117.136
- 6) Recall Plan – §117.139
- 7) Monitoring – §117.145
- 8) Corrective Actions – §117.150
- 9) Verification – §117.155, 165
- 10) Validation – §117.160
- 11) Reanalysis – §117.170
- 12) Records Required – §117.190

Current Good Manufacturing Practices:

- 1) Qualified Individual – §117.4
- 2) Personnel – §117.10
- 3) Plant and grounds – §117.20

- 4) Sanitary operations – §117.35
- 5) Sanitary facilities and controls – §117.37
- 6) Equipment and utensils – §117.40
- 7) Processes and controls – §117.80
- 8) Warehousing and distribution – §117.93, §1.908
- 9) Holding and distribution of human food by-products for use as animal food – §117.95
- 10) Defect action levels – §117.110

Sanitary Transportation of Human and Animal Foods:

- 1) Who is subject to Sanitary Transportation rule? – §1.900
- 2) How does this information apply under the Food, Drug, and Cosmetic Act? – §1.902
- 3) What requirements apply to vehicles and transportation equipment? – §1.906
- 4) What are the general requirements for transportation operations? – §1.908(a)
- 5) What requirements are applicable to shippers engaged in transportation operations? – §1.908(b)
- 6) What are the requirements applicable to loaders and receivers engaged in transportation operations? §1.908(c) and (d)
- 7) What are the requirements applicable to carriers engaged in transportation operations? – §1.908(e)
- 8) What training requirements apply to carriers engaged in transportation operations? – §1.910
- 9) What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations? – §1.912
- 10) How are waiver requests submitted? – §1.914-§1.934

Registration of Food Facilities:

- 1) Who must register? – §1.225
- 2) Who does not have to register? – §1.226
- 3) When must you register or renew your registration? – §1.230
- 4) How and where do you register or renew your registration? – §1.231
- 5) What information is required in the registration? – §1.232
- 6) How and when do you update your facility's registration information? – §1.234
- 7) How and when do you cancel your facility's registration information? – §1.235
- 8) How are waiver requests submitted? – §1.245

Figure 2.

Visual Example of the Food Safety Modernization Act Human Food Audit Checklist: Hazard Analysis and Risk-Based Preventive Controls Part 7 – §117.145

Hazard Analysis and Risk-Based Preventive Controls Part 7 – §117.145

Monitoring		Yes	No	N/A	Documents
7.1	Written procedures must be established and implemented including the frequency with which they				

	are to be performed if a preventive control is identified in the food safety plan.				
	Hint: The protocol should include a description of the products and hazards, what specifications are checked, how it is monitored, when and how often it is checked, and records of monitoring results.				
7.2	Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.				
	Hint: How frequently are thorough checks being performed?				
7.3	Records documenting the monitoring of preventive controls to verify the written procedures.				
	Hint: Check the monitoring documentation. Who is monitoring? Who is checking monitoring? How is the check of monitoring being completed?				

Comments:

Monitoring is a check to ensure the processing of the food is going as expected. Corrective actions (Part 9) are taken when monitoring procedures uncover an issue with the food.

Definitions (§117.3):

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Support for Checklist Format

Gibson, Boelter, Boyce, & LeFebvre (1992) recommended providing learners with helpful hints on how best to use developed materials. Indeed, the supplemental hints in the FSMA Human Food Audit Checklist were found by reviewers of the checklist to be unique and insightful tools for aiding processors' understanding of FSMA by explaining the applications of the law's points rather than simply rewording them. For example, 21 CFR 117.145(a) states "You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control." This statement was extracted as point 7.1 in the Hazard Analysis and Risk-Based Preventive Controls checklist. Information that is not evident upon reading the law was included as the hint: "The protocol should include a description of the products and hazards, what specifications are checked, how it is monitored, when and how often it is checked, and records of monitoring results." This hint gives processors additional information to use in the development of a food safety plan, information that otherwise may not be accessible.

The comments section was also incorporated to provide additional information and tips about each part. Continuing the example used above, the comments section associated with the applicable part reads "Monitoring is a check to ensure the processing of the food is going as expected. Corrective actions (Part 9) are taken when monitoring procedures uncover an issue with the food." These comments weave together the fabric of the checklist. This example references the Corrective Actions part of the checklist and reminds processors of the importance of monitoring in their facilities.

Reviews of Checklist

The checklist received two courtesy reviews by U.S. Food and Drug Administration FSMA subject experts for regulation accuracy. Additionally, members of food safety teams from five food companies reviewed it for clarity and ease of use. Modifications were made to the original checklist on the basis of this feedback. The revised version of the checklist was provided to the reviewers, and they indicated that the final version had improved language, provided guidance for limited-knowledge audiences, and was easy to use within a food facility.

Summary

The FSMA Human Food Audit Checklist was created as a tool for assisting food processing facilities' staff/personnel with FSMA understanding by combining the functionality of a checklist with beneficial information, such as hints, comments, and definitions. The checklist can be modified for use with any regulation and for assisting a specific population with compliance. Additionally, any section of the checklist can be tailored toward specific products for more precise applicability. The checklist also can be divided or simplified to match the personnel knowledge, equipment, and processes related to a particular facility. Extension professionals can use the checklist as part of their technical assistance outreach to food processors or modify it to fit regulations applicable to their various audiences.

Acknowledgments

The work described here was funded by a grant from the Food and Drug Administration (Grant Number 1R01FD005685-01) and a product of the Iowa Agriculture and Home Economics Experiment Station, Hatch Act and State of Iowa funds (Project No. IOW03902).

References

- Gawande, A. (2007, December). The checklist: If something so simple can transform intensive care, what else can it do? *The New Yorker*, 83, 86–101.
- Giampaoli, J., Cluskey, M., & Sneed, J. (2002). Developing a practical audit tool for assessing employee food handling practices. *Journal of Child Nutrition & Management*, 26(2).
- Gibson, C. C., Boelter, L. A., Boyce, L. J., & LeFebvre, J. E. (1992). Teaching consumer credit at home. *Journal of Extension*, 30(3), Article 3FEA3. Available at: <https://joe.org/joe/1992fall.a3.php>
- Grover, A. K., Chopra, S., & Mosher, G. A. (2016). Food Safety Modernization Act: A quality management approach to identify and prioritize factors affecting adoption of preventive controls among small food facilities. *Food Control*, 66, 241–249.
- Haynes, A. B., Weiser, T. G., Berry, W. R., Lipsitz, S. R., Breizat, A. H. S., Dillinger, E. P., & Gawande, A. A. (2009). A surgical safety checklist to reduce morbidity and mortality in a global population. *New England Journal of Medicine*, 360(5), 491–499.
- Levin, B., & Newslow, D. (2013). From HACCP to HARPC—What's best in class and how to get there. Retrieved from <https://safetychain.com/recorded-webinars/haccp-harpc-best-class-get/>
- Reed, D. B., & Schuster, E. (2002). Recipe checklist: A tool to aid development for audiences with limited resources. *Journal of Extension*, 40(6), Article 6TOT4. Available at: <https://joe.org/joe/2002december/tt4.php>
- Shaw, A. M., Strohbehn, C. H., Naeve, L. L., Domoto, P. A., & Wilson, L. A. (2015). Knowledge gained from good agricultural practices courses for Iowa growers. *Journal of Extension*, 53(5), Article 5RIB3. Available at: <https://joe.org/joe/2015october/rb3.php>
- Strohbehn, C. H., Enderton, A., Shaw, A. M., Perry, B., Overdiep, J., & Naeve, L. L. (2018). Determining what growers need to comply with the Food Safety Modernization Act Produce Safety Rule. *Journal of Extension*, 56(7), Article 7RIB1. Available at: <https://joe.org/joe/2018december/rb1.php>

Copyright © by *Extension Journal, Inc.* ISSN 1077-5315. Articles appearing in the Journal become the property of the Journal. Single copies of articles may be reproduced in electronic or print form for use in educational or training activities. Inclusion of articles in other publications, electronic sources, or systematic large-scale distribution may be done only with prior electronic or written permission of the [Journal Editorial Office, joe-ed@joe.org](mailto:joe-ed@joe.org).

If you have difficulties viewing or printing this page, please contact [JOE Technical Support](#)