Conference for Food Protection
2020 Issue Form

Issue: 2020 II-030

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Issue History:

This is a brand new Issue.

Title:

Creation of a Food Safety Management System (FSMS) Committee

Issue you would like the Conference to consider:

The FDA Food Code emphasizes the need for risk-based preventive controls and daily active managerial control (AMC) of the risk factors contributing to foodborne illness in food establishments. AMC is "the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors" (FDA, 2018). AMC involves the proactive identification and prevention of food safety hazards through a continuous system of monitoring and verification procedures for performing critical operational steps in a food preparation process. Two strategies supporting AMC efforts in food establishments have received growing attention: The presence of a Certified Food Protection Manager (CFPM) and the implementation of Food Safety Management Systems (FSMSs).

FSMS refers to the incorporation of a specific set of actions (e.g., procedures, training, monitoring, and verification) to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors in food establishments. While FSMS procedures vary across the retail and food service industry, purposeful implementation of procedures, training, and monitoring are consistent components of FSMSs. While several systems and tools are available internationally, including International Organization for Standardization (ISO 22000), Good Manufacturing Practices (GMP), Hazard Analysis and Critical Control Point (HACCP), British Retail Consortium (BRC) and Safe Quality Food Institute (SQF) (Codex, 2003; ISO 22000:2005, 2005; Luning et al., 2008), the ongoing prevalence and degree of implementation of these or similar systems within foodservice and retail food establishments in the United States remains understudied.

Inadequate FSMSs are thought to contribute to the worldwide burden of foodborne disease (Luning et al., 2008). For example, HACCP has been shown to have positive effects on food safety, but the poor implementation of HACCP has been described as a precursor to foodborne outbreaks (Cormier, 2007; Luning et al., 2009; Ropkins and Beck, 2000).

The 2013-2024 FDA Retail Food Risk Factor Study examines the occurrence of foodborne illness risk factors, food safety practices, and behaviors in food establishments. In the 2013-2014 Restaurant Data Collection study, the agency investigated the relationship between FSMSs, CFPM, and the occurrence of foodborne illness risk factors from 2013 to 2014. FSMSs were the strongest predictor of data items being out-of-compliance in both fast food and full-service restaurants. The average number of out-of-compliance data items was greatly reduced when there was a well-developed FSMS in place. This was true for both fast food restaurants and full-service restaurants. On average, restaurants with well-developed FSMSs had less than half as many risk factors and food safety practices that were out-of-compliance than restaurants with non-existent FSMSs.

The FDA has endorsed the voluntary development and implementation of documented food safety management systems in food establishments for many years:

1. *Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments* was first published in 1998 and has been endorsed by the Conference for Food Protection (CFP).
2. In the 2005 FDA Food Code, Annex 4, "Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors," was revised to further promote the voluntary development and implementation of documented FSMSs using HACCP principles as a tool to achieve AMC in food establishments. In June 2014, the restaurant members of the FDA-Restaurant Industry Partnership Group provided feedback to the FDA for updating Annex 4. Specifically, the group provided feedback on "what industry models are in use for AMC and are these in line with Annex 4?" and "what works in Annex 4 and what is not a fit?" In general, the industry members suggested that AMC should be viewed as a "system" for process management, as defined in Annex 4, to include HACCP as the approach. Other suggestions included: 1) To consider including "Demonstration of Knowledge" by the Person in Charge as a way to manage/control processes and qualify as AMC; 2) Consider including food handler training and the topic of food defense in the criteria for AMC; 3) Specific to "how can the occurrence of foodborne illness risk factors be reduced," suggest encouraging the following four topics/steps: instituting food safety standards, training to the standards, executing the standards, and verifying that the standards are being executed.
3. Following the October 2010 release of the *FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998-2008)*, the FDA launched its Retail Food Safety Initiative which further emphasized the need for industry to establish food safety management systems and actively monitor compliance with those systems to reduce the occurrence of risk factors in retail operations.
4. Recognizing the importance of FSMSs in managing food safety hazards, since 2005, USDA has required that all public schools have in place a food safety plan based on process HACCP principles. Schools that do not meet this mandate are in jeopardy of losing their federal funds. The FDA collaborated with USDA on the development of the food safety plan model.

Despite over 20 years of promotion of voluntary FSMSs, widespread adoption of the Food Code across the U.S., and other ongoing food safety prevention efforts at the retail level,

foodborne illness from retail establishments continues to be a substantial public health burden that must be addressed in novel ways.

FDA has announced a New Era of Smarter Food Safety that includes examining new retail models and retail modernization in an effort to reduce foodborne illness at the retail level. The agency intends to publish a blueprint for this effort early in 2020. To support this effort, the FDA is recommending the formation of a CFP committee to provide recommendations to the agency on how best to promote the universal development and implementation of documented, HACCP principles-based FSMSs in food establishments.

Public Health Significance:

- Foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths each year (Scallan et al., 2011). Depending on the estimation model used, the annual economic burden from health losses due to foodborne illness ranges from $51.1 billion to $77.7 billion (Scallan, 2012).
- From 2015 - 2018, the incidence of foodborne infections remained largely unchanged.[1]
- Of the approximately 9.4 million illnesses each year in the United States traced to known foodborne disease agents, only a small subset of illnesses are associated with recognized outbreaks. During 2009-2015, the Foodborne Disease Outbreak Surveillance System (FDOSS) received reports of 5,760 outbreaks, resulting in 100,939 illnesses, 5,699 hospitalizations, and 145 deaths. A location of preparation was provided for 5,022 outbreak reports (87%), with 4,696 (94%) indicating a single location. Consistent with previous reporting periods, among outbreaks reporting a single location of preparation, restaurants were the most common location (2,880 outbreaks [61%]), followed by catering or banquet facilities (636 [14%]) and private homes (561 [12%]). Sit-down dining style restaurants (2,239 [48%]) were the most commonly reported type of restaurant. The locations of food preparation with the most outbreak-associated illnesses were restaurants (33,465 illnesses [43%]), catering or banquet facilities (18,141 [24%]), and institutions, such as schools (9,806 [13%]). The preparation location with the largest average number of illnesses per outbreak was institutions (46.5), whereas restaurants had the smallest (11.6) (Dewey et al., 2018).
- In 2017, 841 foodborne disease outbreaks were reported by 50 states, Washington, D.C., and Puerto Rico, resulting in 14,481 illnesses, 827 hospitalizations, 20 deaths, and 14 food recalls. Among the 761 outbreaks and 12,502 illnesses with a reported single location where food was prepared, 489 outbreaks (64%) and 5,533 associated illnesses (44%) were attributed to foods prepared in a restaurant. Among these single-location outbreaks, restaurants with sit-down dining were most commonly reported as the location where food was prepared (366 outbreaks, 48% of the outbreaks). (CDC, 2019)

In a study of restaurant-associated outbreaks in the United States from 1998-2013, Angelo, Nisler, Hall, Brown and Gould (2016) identified 9,788 restaurant-associated outbreaks, with a median of 620 outbreaks per year. Norovirus caused 46% of the 3,072 outbreaks associated with a single, confirmed etiology. Activities related to food handling and

preparation practices were the most commonly reported contributing factors within restaurant-associated outbreaks

Recommended Solution: The Conference recommends...:

A Food Safety Management System (FSMS) Committee be created to identify recommendations for developing and implementing documented, HACCP principles-based Food Safety Management Systems (FSMSs) in all food establishments to support FDA's blueprint for a New Era of Smarter Food Safety. The FSMS Committee should consider:

1. Identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.
2. Identifying solutions for overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions.
3. Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on: a) the hurdles/challenges involved in such a requirement; and b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.
4. Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.

The committee should report its findings and recommendations to the 2022 Biennial Meeting of the Conference for Food Protection. While FDA's efforts will be ongoing during this time, the findings and recommendations will continue to be useful to the agency as it continues to implement its blueprint on retail modernization.

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Supporting Attachments:

- "Reference Sheet"

Marder, MPH EP, Griffin PM, Cieslak PR, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006–2017. MMWR Morb Mortal Wkly Rep 2018;67:324–328. DOI: http://dx.doi.org/10.15585/mmwr.mm6711a3external icon

Angelo KM; Nisler AL; Hall AJ; Brown LG; Gould LH. Epidemiology of restaurant-associated foodborne disease outbreaks, United States, 1998-2013. Epidemiol Infect. 2017; 145(3):523-534.

Tack DM, Marder EP, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2015–2018. MMWR Morb Mortal Wkly Rep 2019;68:369–373. DOI: http://dx.doi.org/10.15585/mmwr.mm6816a2external icon.

Dewey-Mattia D, Manikonda K, Hall AJ, Wise ME, Crowe SJ. Surveillance for Foodborne Disease Outbreaks — United States, 2009–2015. MMWR Surveill Summ 2018;67(No. SS-10):1–11. DOI: http://dx.doi.org/10.15585/mmwr.ss6710a1external icon

Centers for Disease Control and Prevention (CDC). Surveillance for Foodborne Disease Outbreaks, United States, 2017, Annual Report. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC, 2019.
https://www.cdc.gov/fdoss/pdf/2017_FoodBorneOutbreaks_508.pdf

Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis. 2011;17(1):7-15.
https://dx.doi.org/10.3201/eid1701.p11101

Scharff, Robert L. Economic Burden from Health Losses Due to Foodborne Illness in the United States. Journal of Food Protection, Vol. 75, No. 1, 2012, Pages 123–131.

Food and Drug Administration (2018). FDA Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-service Restaurants, 2013-2014.
https://www.fda.gov/media/117509/download

Food and Drug Administration (2010). FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998-2008). https://www.fda.gov/media/117509/download

Ropkins, K., and Beck, A.J. (2000). Evaluation of Worldwide Approaches to the Use of HACCP to Control Food Safety. *Trends in Food Science & Technology, 11(1),* 10-12.

Cormier, R.J., Mallet, M., Chiasson, S., Magnusson, H., and Valdimarsson, G. (2007). Effectiveness and Performance of HACCP-based Programs. *Food Control, 18(6)*, 665-671.

International Organization for Standardization (2005). ISO 22000:2005. *Food Safety Management Systems – Requirements for any Organization in the Food Chain*. Retrieved from: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=35466.

Food and Drug Administration. Food Code 2017. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2018.
https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm595139.htmexternal icon.

Luning, P.A., Bango, L., Kussaga, J., Rovira, J., and Marcelis, W.J. (2008). Comprehensive Analysis and Differentiated Assessment of Food Safety Control Systems: A Diagnostic Instrument. *Trends in Food Science & Technology, 19(10),* 522-534.

Luning, P.A., Marcelis, W.J., Rovira, J., Van der Spiegal, M., Uyttendaela, M., and Jacxsens, L. (2009). Systematic Assessment of Core Assurance Activities in a Company-specific Food Safety Management System. *Trends in Food Science & Technology, 20(6),* 300-312.