

The National Environmental Health Association (NEHA) represents more than 7,000 governmental, private, academic, and uniformed services sector environmental health professionals in the U.S., its territories, and internationally. NEHA is the profession's strongest advocate for excellence in the practice of environmental health as it delivers on its mission to build, sustain, and empower an effective environmental health workforce.

Policy Statement on the Enrollment and Conformance With the Food and Drug Administration Voluntary National Retail Food Regulatory Program Standards

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The goal of all retail food regulatory programs is to reduce or eliminate the occurrence of illness and deaths from food produced at the retail level (Food and Drug Administration [FDA], 2020a). There are more than 3,000 state, local, tribal, and territorial governmental agencies that have the primary responsibility of regulating the retail food and food service industries in the U.S. (FDA, 2020a). The U.S. has made several strides towards national uniformity among regulatory food programs responsible for retail food protection by having states adopt the Food and Drug Administration (FDA) *Food Code* and producing widely recognized standards for regulatory food programs that administer the *Food Code* (FDA, 2019a). The FDA Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) is a tool available for retail food regulatory programs that aids in the overarching goal of foodborne illness reduction nationwide.

The Centers for Disease Control and Prevention (CDC) estimates that foodborne illness causes approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the U.S. each year (CDC, 2018). As of 2019, FDA reports that eight states have adopted the most recent version of the *Food Code* (FDA, 2019b). Enrollment in the Retail Program Standards can help retail food regulatory programs prevent foodborne illness and deaths in their communities by driving improvements in the way food is prepared and served in food service and retail food establishments (National Association of County and City Health Officials, 2014). Enrollees have access to a variety of resources and funding opportunities, and are effecting change at the state level by encouraging the adoption of the current *Food Code*. The Retail Program Standards encourage regulatory agencies to improve and build upon existing programs (FDA, 2019a). The Retail Program Standards are intended to reinforce proper sanitation and operational and environmental prerequisite programs while encouraging regulatory agencies and industry to focus on the factors that cause and contribute to foodborne illness with the ultimate goal of reducing the occurrence of those factors (FDA, 2019a).

NEHA's Policy Statement

NEHA recommends all federal, state, local, tribal, and territorial governmental agencies to enroll in the Retail Program Standards to implement current national standards that outline a process of program self-assessment and continuous improvement of existing regulatory program measures to help reduce foodborne illness risk factors. Enrollment and conformance ensure the safety and security of the food supply at the retail level.

NEHA recommends the following for federal, state, local, tribal, and territorial governmental agencies:

- Complete adoption and implementation of the most current FDA *Food Code* to achieve national uniformity in a regulatory framework.
- Enroll in the FDA Voluntary National Retail Food Regulatory Program Standards.
- Ensure resources are available to achieve and maintain all nine components of the FDA Voluntary National Retail Food Regulatory Program Standards.
- Seek additional funding opportunities to meet and/or maintain the FDA Voluntary National Retail Food Regulatory Program Standards.

Analysis

The FDA Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) define what constitutes a highly effective regulatory food safety program at the state, territorial, local, and tribal levels (FDA, 2020b). The Retail Program Standards provide a foundation for regulatory agencies to build upon existing programs by promoting a continuous improvement process (FDA, 2020b). The Retail Program Standards represent FDA recommendations for the design and management of retail food regulatory programs that aim to provide tools to help agencies identify program areas that need improvement.

The need for nationally uniform retail food regulatory programs has been recognized by environmental health professionals and consumers alike (FDA, 2019a). In order to address the need for national uniformity, FDA developed the *Food Code*. The *Food Code* represents FDA recommendations for a uniform system of regulation to ensure that food at the retail level is safe for consumers (U.S. Department of Health and Human Services [HHS], 2017). Providing model food codes and *Food Code* interpretations are the mechanisms through which FDA promotes uniform implementation of national retail food regulatory policy among the several thousand federal, state, local, tribal, and territorial agencies that have primary responsibility for the regulation or oversight of retail level food operations (HHS, 2017). The *Food Code* assists jurisdictions by providing them with a scientifically sound technical and legal basis for regulating the retail segment of the food industry (FDA, 2019c). Using the *Food Code* as a model, jurisdictions design their food safety regulations to be in conformance with national retail food regulatory policy (FDA, 2019c).

Where the adoption of the *Food Code* is key in the effort to encourage national uniformity among regulatory programs responsible for retail food protection in the U.S., the Retail Program Standards were created to address the need for a standardized set of guidelines for these regulatory programs (FDA, 2019a). Since the Retail Program Standards are voluntary, they do not carry legal weight like laws or regulations. Rather, they are used as guidelines for regulatory agencies to measurably improve their existing programs and better focus on reducing the risk factors that contribute to foodborne illness.

The Retail Program Standards consist of nine standards of excellence for the continued improvement of retail food regulatory programs (FDA, 2020c). The Retail Program Standards were designed with the goal of all retail food regulatory agencies in mind to reduce the incidence of foodborne illness risk factors and death due to foodborne illness from food sold or served at the retail level (FDA, 2019a). Enrollment in the Retail Program Standards aids in reaching this common goal through the promotion of a regulatory foundation, regulatory staff training, a risk-based inspection program, a uniform inspection program, foodborne illness response and preparedness, compliance and enforcement measures, community engagement, and self-assessment of programs. The Retail Program Standards recognize the differing needs of regulatory agencies at the federal, state, local, tribal, and territorial levels, and aim to lay a foundation for excellence in traditional and emerging food safety practices. Ultimately, the guidelines set forth in the Retail Program Standards will help regulatory agencies reduce foodborne illness risk factors by ensuring agency conformance with FDA best practices.

Today, there are 835 jurisdictions enrolled in the Retail Program Standards working towards reaching the gold standard of retail food regulation (FDA, 2020b). FDA has grants and cooperative agreements available to jurisdictions to address barriers to enrollment, such as limited resources, budgets, and staffing. In cooperation with FDA, the National Association of County and City Health Officials (NACCHO) has developed a mentorship program to help jurisdictions with conformity to the Retail Program Standards. There is also a crosswalk between the Public Health Accreditation Board (PHAB) process and the Retail Program Standards that incentivizes enrollment by allowing for documents from the Retail Program Standards to be used for the PHAB process, which ultimately saves jurisdictions time, money, and resources. These supplemental programs aid in promoting the common goal of foodborne illness reduction by encouraging enrollment and conformance with the Retail Program Standards.

Justification

Although the U.S. is considered one of the safest countries in the world to consume food at the retail level, CDC estimates approximately 48 million people get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases annually (CDC, 2018). In addition to the burden foodborne disease has on public health, the U.S. Department of Agriculture's Economic Research Service (2020) estimates the economic cost of foodborne disease in the U.S. to be \$15.6 billion annually. More than one half of all costly foodborne illness outbreaks are connected to retail food establishments (Angelo, Nisler, Hall, Brown, & Gould, 2017).

CDC has identified the five leading causes of foodborne illness outbreaks in retail food settings: improper holding temperatures of food, improper cooking temperatures, contaminated utensils and equipment, food from unsafe sources, and poor employee health and hygiene. Failure to exclude ill employees from working until they have been symptom free for 24 hours accounts for nearly 46% of all restaurant-associated outbreaks (Angelo et al., 2017). Improper hand washing by food service employees accounts for another 30% of restaurant-associated outbreaks (Angelo et al., 2017). The *Food Code* establishes provisions to address and reduce these five leading causes of foodborne illness outbreaks. In a state-by-state assessment of food service regulations, states that adopted these provisions reported fewer foodborne illness outbreaks than states that had not adopted the provisions set forth by the *Food Code* (Kambhampati et al., 2016). Enrollment and conformance with the Retail Program Standards will ensure adoption of these provisions by encouraging full adoption of the *Food Code*.

National uniform adherence with FDA retail food regulation best practices, like the *Food Code* and Retail Program Standards, has the potential to decrease the occurrence of foodborne illness outbreaks (Kambhampati et al., 2016). The Retail Program Standards provide a clear set of evidence-based guidelines for self-assessment and continuous improvement of regulatory agency programs and processes (FDA, 2019b). Enrollment with the Retail Program Standards has the potential to aid in the reduction of foodborne illness incidence by providing standardized training, program evaluation, and technical support for jurisdictions. Conformance with the *Food Code* and Retail Program Standards encourages the use of a standardized set of guidelines for food safety that has the potential to increase compliance with key risk reduction measures (FDA, 2019a).

The Retail Program Standards provide an evidence-based curriculum for training regulatory staff on laws and regulations, public health principles, food safety, communication, and inspections protocols (FDA, 2019a). The Retail Program Standards encourage uniform training of regulatory food inspection personnel as a means to reduce variability between inspectional staff during inspection, thus ensuring inspectors recognize hazards appropriately and are equipped with the tools and knowledge needed to carry out a risk-based inspection. This training likely reduces the probability of foodborne disease outbreak and increases the overall efficiency of the regulatory program.

Enrollment in the Retail Program Standards assists regulatory agencies in reducing risk factors by outlining a standardized inspection program based on the hazardous analysis critical control points (HACCP) system. Modeling inspection procedures on this systematic approach to prevent foodborne disease outbreaks will allow regulatory staff to easily identify risk factors and effectively implement any necessary corrective action. Encouraging regulatory agencies to develop a standardized inspection program ensures uniformity of implementation, evaluation, and interpretation of inspections from regulatory staff (FDA, 2019a). Having an established inspection program designed to target the risk factors most associated with foodborne illness will reduce any confusion associated with the inspection process, thus reducing the likelihood of overlooking a critical food safety violation during an inspection.

In a key informant interview conducted by NACCHO, jurisdictions enrolled in the Retail Program Standards reported improving the quality and consistency of service provided by environmental health specialists working with retail food establishments (National Association of County and City Health Officials [NACCHO], 2014). Jurisdictions also reported that utilizing the tools provided by the Retail Program Standards, like sample documents and training materials, saved valuable time and resources (NACCHO, 2014). The guidance and foundation provided by the Retail Program Standards allows retail food safety programs to operate more efficiently while simultaneously ensuring quality improvement of services focused on reducing the occurrence of foodborne illness.

While enrollment in the Retail Program Standards is not legally mandated, NEHA encourages enrollment and conformance with all the standards. Benefits of enrollment in the Retail Program Standards include enhancing relationships with industry, improving quality and consistency of services, using existing resources more efficiently, adopting technology to keep better records of inspections, and affecting change at the state level through advocating for changes to the *Food Code* (NACCHO, 2014). Using a standardized set of guidelines for retail food regulatory programs to be built upon will ensure limited consumer exposure to risk factors associated with foodborne disease.

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