

CHAPTER 18 – TECHNICAL ASSISTANCE

SUBJECT:	RETAIL FOOD PROTECTION – STATE (FY 12/14)
IMPLEMENTATION DATE:	9/29/2025
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODE: 51NY	<p>Under PAC 18002, Report the Following Operations into FACTS:</p> <p>83 – Training/Education GIVEN by FDA Personnel 84 – Training RECEIVED by FDA Personnel 86 – Detail 92 – Coordination / Technical Assistance 95 – Program Evaluation 96 – Standardization or Certification of Non-FDA Personnel</p> <p>Report counter terrorism activities under PAC 18R845</p> <p>Report partnership/grant activities under PAC 18R834</p>

FIELD REPORTING REQUIREMENTS - FDA REGIONAL FOOD SPECIALISTS

Instructions provided in Parts II and III provide for the following reports:

A. REPORTS TO HEADQUARTERS Reports to HFP/Office of Integrated Food Safety Systems and Partnerships (OIFSSP), Office of Retail Food Protection (ORFP), Division of Retail Food Protection Policy, Research and Risk Assessment (DRFPPRRA)

1. Compliance Program Status Reports (Attachment A)
2. Regional Program Standards Status Report (reported electronically using FDA Program Standards Reporting Form Template (Attachment B) and posted on FDA Web site. Status Reports are based on Program Standards updates submitted by enrolled jurisdictions using the FDA National Registry Report 3519 and Release Record and Agreement – Permission to Publish in National Registry 3520

3. Report of Adoption of the Recommended Model 3520
4. Copy of Notification letter for successful standardization of state officials and copy of Standardization Certificate (see Part III.2.B)

List of state officials meeting Standardization Certification criteria. (See Part III.2.B)

Regional Work Plan information that contributes to the National Office of Retail Food Protection FY Work Plan (see Part II.2.E.), Submit to the Field Programs Branch,

B. HARDCOPY REPORTS TO STATE OFFICIALS

1. Notification letter for successful standardization of state officials and Standardization Certificate (see Part III.2.B.)
2. Certificates for achieving significant benchmarks in the Program Standards initiative.

Note: The use of “state” throughout this compliance program also implies local and tribal.

PART I - BACKGROUND

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The FSMA builds a formal system of collaboration with other government agencies. In doing so, the statute explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals.

FDA serves as the lead federal agency of the National Retail Food Program. The FDA National Retail Food Team is one of the Cooperative Programs within FDA and comprises headquarters representatives from OII within the Office of Domestic Partnerships (ODP), the Office of Training, Education and Development(OTED),from FDA's Human Foods Program(HFP),Office of Integrated Food Safety Systems and Partnerships(OIFSSP),Office of Retail Food Protection (ORFP)and Office of Inspections and Investigations(OII) representatives from the field via the Retail Food Specialist. The National Food Protection Program includes FDA and other federal, state, local, and tribal regulatory agencies, industry, and academia. The purpose of the FDA National Retail Food Team is to develop and implement strategies to leverage and enhance the food safety and defense capacities of state/local/tribal regulatory retail food protection programs. In addition, the National Retail Food Team seeks to form cooperative working relationships with the foodservice and retail food industries to promote the implementation of effective food safety management systems.

The scope of FDA's retail food safety mission impacts over 2,300 state, local, tribal, and territorial regulatory jurisdictions, encompassing over 27,000 regulators; 960,000 restaurants, which serve more than 70 billion meals and snacks each year, with sales topping \$604 billion dollars¹; ~215,000 supermarkets, small grocery stores, and convenience stores²; over 101,000 public and non-profit private schools (grades K-12), which served 5 billion lunches, and 214 million after school snacks in 2009³; ~5,795 hospitals⁴; and ~17,000 nursing home facilities⁵.

FDA's role in providing assistance to state and local governments is derived from the Public Health Service Act (PHS) (PL 78-410) and [42 USC 243, Section 311(a)] [Also 21 CFR 5.10(a)(2) and (4)]. Responsibility for carrying out the provisions of the PHS Act relative to food protection was transferred to the Commissioner of Food and Drugs in 1968 (21 CFR 5.10(a) (2) and (3)). The regulatory functions of FDA's National Retail Food Team are sanctioned by the Act which requires that the Department via the Secretary take actions to assist state and local entities. In response, the FDA serves to provide assistance to states and their political subdivisions relative to the prevention and suppression of communicable diseases. In addition, with respect to other public health matters, the Act requires that FDA cooperate with and aid state and local authorities in

the enforcement of their health regulations and provide advice on matters relating to the preservation and improvement of public health. Additionally, the Federal Food, Drug, and Cosmetic Act [21 USC 301] and Economy Act [31 USC 1535] require that FDA provide assistance to other Federal, state, and local governmental bodies.

Lastly, Sections 301(k) and 704 of the Federal Food, Drug, and Cosmetic Act (Act) provide authority to FDA to inspect retail food establishments where food is held for sale after its shipment in interstate commerce. Findings of adulterated or misbranded food further provide FDA with the authority to take enforcement action.

It is estimated that foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the U.S. each year⁶. The estimated cost of foodborne illness is \$77 billion annually⁷. Of the 6,647 foodborne disease reported outbreaks that occurred from 1998 - 2002, >46% were definitively attributed to restaurants, delicatessens, groceries, cafeterias, or schools⁸. The CDC Surveillance Report for 1998 - 2002 identified the most significant contributing factors to foodborne disease outbreaks in which contributing factors were reported during that period^{7,8}. Five of these broad categories of contributing factors directly relate to food safety concerns in retail and foodservice establishments and are collectively termed by FDA as “foodborne illness risk factors.” The foodborne illness risk factors are:

- Food from Unsafe Sources;
- Inadequate Cooking Temperatures;
- Improper Holding Temperatures;
- Contaminated Equipment/Cross-contamination; and
- Poor Personal Hygiene.

The 1993 Government Performance and Results Act required federal agencies to develop performance plans that included measurable goals and performance indicators. In response, the FDA National Retail Food Steering Committee was formed in 1996 to establish a strategic plan for the national retail food program, including the FDA National Retail Food Team Operational Plan and the FDA National Retail Food Team Specialists Work Plan. In order to provide the basis for the development of a performance measurement for assessing the effectiveness of the nation's retail food protection system over time, the FDA National Retail Food Team conducted a ten-year nationwide study (1998 –2008) to measure trends in the occurrence of foodborne illness risk factors^{10,11,12}. Using the results from this 1998 data collection as a baseline, data for three collection periods (1998, 2003, and 2008) were analyzed to detect improvement over the ten-year study period¹³. The Steering Committee established a performance goal of *reducing the occurrence of foodborne illness risk factors in institutional foodservice, restaurants, and retail food establishments by 25% by 2010*

The data in the *2009 FDA Trend Analysis Report on the Occurrence of Foodborne illness Risk Factors within Institutional Foodservice, Restaurant, and Retail Food Store Facility Types* suggest that control of certain foodborne illness risk factors improved over the 10-

year period in most facility types, but that compliance with important requirements in the *FDA Food Code* needs further improvement in order to adequately prevent foodborne illness outbreaks. Despite significant improvements in many facility types, three risk factors – Improper Holding/Time and Temperature, Poor Personal Hygiene, and Contaminated Equipment/Protection from Contamination – continue to be most in need of priority attention by both industry and the regulatory community.¹²

FDA's National Retail Food Safety Initiative, announced in October 2010, is part of the agency's overall prevention-based, farm-to-table food safety strategy to reduce foodborne illness. FDA's actions in this initiative are prompted by its 10-year study of more than 800 institutional foodservice, restaurant, and retail food establishments to assess the control of the five foodborne illness risk factors. FDA partnerships with the retail food industry, state, local and tribal authorities, and other government agencies are fundamental to this initiative and key to its success.

FDA's Retail Food Safety Initiative identifies four key action areas:

1. Make the presence of certified food protection managers common practice
2. Strengthen active managerial control at retail and ensure better compliance
3. Encourage widespread, uniform, and complete adoption of the *FDA Food Code*
4. Create an enhanced local regulatory environment for retail food operations

The FDA Retail Food Safety Initiative action plan, posted in September 2011 and available at <http://www.fda.gov/media/157226/download?attachment>, outlines several strategies FDA plans to implement over the next several years within these four action areas. The National Retail Food Team has several parallel initiatives aimed at reducing the occurrence of foodborne illness risk factors including the development and issuance of the *FDA Food Code* and supporting guidance documents, the training of stakeholders, and the development and implementation of Voluntary National Retail Food Regulatory Program Standards (Program Standards). Strategies used to effectively implement these initiatives are formulated through national team meetings, national conferences, and work group activities.

1. Make the presence of certified food protection managers common practice

The data from FDA's 10-year study on the occurrence of foodborne illness risk factors indicates that for some facility types, there is a positive correlation associated with having a certified food protection manager (CFPM) and control of one or more foodborne illness risk factors. Many states and localities require a CFPM and many in the retail industry employ them voluntarily as a matter of good practice. Some National Retail Food Program Strategies to achieve this goal include: Working with the Conference for Food Protection (CFP) to expand the presence of CFPMs in retail food and foodservice establishments.

- Working with our cooperative program partners to encourage and facilitate the development of effective training and certification for CFPMs in retail food and foodservice establishments.
- Forming cooperative working relationships with stakeholder groups and the industry to analyze and address challenges of providing training for a workforce with high turnover and with various educational and cultural backgrounds.

2. Strengthen active managerial control at retail and ensure better compliance

As a result of the Food Safety Modernization Act (FSMA), FDA has a legislative mandate to require comprehensive, science-based preventive controls across the food supply. Although this legislative mandate is initially focused on the manufactured food industry's implementation of written preventive control plans, efforts are needed to enhance the implementation of food safety management systems within the retail food industry. FDA's National Retail Food Team is designing its next 10-year foodborne illness risk factor study to include an assessment of impact of food safety management systems on the active managerial control of risk factors in retail food and foodservice facilities. Additional research efforts to strength active managerial control of foodborne illness risk factors at the retail level to ensure better compliance include:

- Working with FDA's Cooperative Program partners, the retail food industry, and academia to assess the effectiveness of various managerial control strategies.
- Developing mechanisms for sharing best practices with the retail industry and state/local/tribal retail food protection programs
- Working with the Conference for Food Protection to consider modifications to the *FDA Food Code* to promote best practices.

3. Encourage widespread, uniform, and complete adoption of the *FDA Food Code*

The *FDA Food Code* represents the Agency's policy and best science-based advice for a uniform system of provisions that address the safety and protection of food served or sold at the retail level. Adoption of the Food Code is a positive representation of a successful model for federal/state/local partnerships in improving food safety. Adoption of the *FDA Food Code* by the military and all food safety agencies at the federal, state, local and tribal levels establish a sound regulatory foundation and legal framework for uniformity in achieving a reduction in the occurrence of foodborne illness risk factors. In support of this initiative, FDA issues interpretations of the *Food Code* and standardizes federal, state, local, and tribal officials in the use of the *Food Code* and HACCP principles in conducting risk-based inspections. FDA also provides training, develops guidance materials and tools, and offers support in such topics as the *FDA Food Code*, HACCP, risk-based inspection methodology, specialized processes, and foodborne illness investigation.

4. Create an enhanced local regulatory environment for retail food operations

FDA, with input from Federal, state, and local regulatory officials, industry, trade associations, academia, and consumers, developed the *FDA Voluntary National Retail Food Regulatory Program Standards* (Program Standards). Designing and/or assessing a retail food regulatory program against the criteria set forth in the Retail Food Program Standards accomplishes two objectives. First, the Retail Food Program Standards promote the active managerial control of foodborne illness risk factors by industry. Secondly, the Retail Food Program Standards establish a recommended framework for retail food regulatory programs within which the active managerial control of foodborne illness risk factors can best be achieved.

Using the Retail Food Program Standards, state, local, and tribal jurisdictions strive to achieve the requirements specified for each of the Standards through a continuous improvement model. As a jurisdiction conducts a self-assessment of its regulatory retail food program with the criteria in each of the nine Standards, the jurisdiction will have a measure of its adequacy in implementing and administering its regulatory program in relation to its:

1. Regulatory Foundation (i.e. *FDA Food Code* or equivalent)
2. Trained Regulatory Staff
3. Inspection Program Based on HACCP Principles
4. Uniform Inspection Program
5. Foodborne Illness & Food Defense Preparedness and Response
6. Compliance and Enforcement
7. Industry and Community Relations
8. Program Support and Resources
9. Program Assessment

By implementing strategies that address the four FDA Retail Food Safety Initiative action areas, FDA's National Retail Food Team supports state, local, and tribal jurisdictions in improving the infrastructure and uniformity of the nation's retail food protection system. This cooperative partnership remains critical to reducing foodbourne illness in the U.S.

References

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PART II - PROGRAM

1. GUIDING PRINCIPLES

The guiding principles that structure the activities of the Agency's cooperative Retail Food Program are:

- Making the most effective and efficient use of resources through participation in collaboration, partnerships, and leveraging with regulatory retail food programs.
- Establishing program priorities based on the extent of actual or potential risk and public health benefit.
- Strengthening the food regulatory agencies' capability to make accurate risk assessments and sound management decisions that are based on the Food Safety Modernization Act (FSMA) and the FDA National Retail Food Safety Initiative in the areas of prevention, intervention and response.
- Being responsive to the needs of the Program partners.

2. ACTIVITIES

Activities assigned to the field to accomplish program objectives based on these guiding principles include:

A. **Promoting Voluntary National Retail Food Regulatory Program Standards (Standards)**. The National Retail Food Team has developed nine program standards:

<https://www.fda.gov/food/retail-food-protection/voluntary-national-retail-food-regulatory-program-standards>(that are deemed necessary for conducting an effective regulatory retail food program. These nine program standards are as follows: 1) Regulatory Foundation; 2) Trained Regulatory Staff; 3) Inspection Program Based on HACCP Principles; 4) Uniform Inspection Program; 5) [Foodborne Illness and Food Defense, Preparedness and Response](#); 6) Compliance and Enforcement; 7) Industry and Community Relations; 8) Program Support and Resources; and 9) Program Assessment. These Standards have been promoted nationally to the approximately 2,300 state, local, and tribal agencies that have retail food regulatory programs.

Retail Food Specialists promote enrollment in the Program Standards to jurisdictions not currently enrolled, including preparation for and delivery of face-to-face meetings, presentations, workshops, conference calls, or any other contact

with jurisdictions with the primary purpose of soliciting their enrollment and participation. Retail Food Specialists provide technical assistance and consultation to currently enrolled jurisdictions, including preparation for and delivery of face-to-face meetings, presentations, workshops, conference calls, or any other contact with jurisdictions with the purpose of assisting them with completing their self-assessments, strategic plans, verification audits, and/or risk factor studies; oversight activities and infrequent verification audits performed directly by FDA Food Specialists. Retail Food Specialists serve as technical advisors on any grants/cooperative agreements awarded to enrolled jurisdictions, including assistance on projects, review of reports, and recommendation for continuation of funding.

B Conducting Field Inspections/Data Collections and Assisting in Studies on the Occurrence of Foodborne Illness Risk Factors.

Retail Food Specialists conduct data collection activities in institutional foodservice, restaurant, and retail food establishments as necessary to complete studies on the occurrence of foodborne illness risk factors. This activity forms the basis for performance measures assessing the effectiveness of the retail food protection system.

- A. Conducting Food Code Standardizations.** Training regulatory officials through standardization of key personnel on the interpretation and application of the *Food Code* provides a solid foundation for a uniform regulatory retail food program. *Food Code* Standardizations incorporate a risk-based inspection methodology and are based on the principles of HACCP.
- D. Implementing HFP Food Safety Priorities.** The Retail Food Specialists provide technical assistance and testimony in support of *Food Code* adoptions. The Specialists, when requested, act as the liaisons between FDA's HFP and the states regarding highly technical matters involving *Food Code* interpretations and special food safety projects identified as priorities by HFP. For the immediate future, maintaining retail food protection as a model for an integrated food safety system, implementing the FDA Retail Food Safety Initiative, updating of the *Food Code*, engaging the Conference for Food Protection, and maintaining the Program Standards remain Center priorities. Other priorities will be identified through the annual work plan.
- E. Developing Program Standards and Guidance.** The Specialists assist the Center in the development of Agency procedures and guidance documents related to the Program Standards, Standardization Procedures, Pre-standardization Workshops, HACCP at Retail, and Specialists' Certification. The support includes the commitment to designate two Specialists to represent the field component on the National Retail Food Team Steering Committee and work group members to carry out necessary activities in support of the National Retail Food Team (NRFT).

F. **Conducting Training Courses.** Training courses will be coordinated and primarily delivered by OTED via a cadre of representatives from the NRFT, including the Specialists and HFP representatives. These courses address the specific needs of our cooperative program partners including, but not limited to, the Program Standards, the *Food Code*, Preparation for Retail Food Standardization, Managing Retail Food Safety utilizing HACCP principles, Foodborne Illness Investigations, Plan Review, Temporary Food Establishments, Risk-Based Inspection Methods, and Special Processes.

3. PROGRAM MANAGEMENT INSTRUCTIONS

A. Establishing A Cooperative Relationship

Responsibility for advising top state officials on matters relating to the preservation and improvement of the public health and for assisting states is an obligation of the Agency under the PHS Act. FDA Regional officials carry out the necessary planning and implementation of program operations performed under this Compliance Program.

States are not obligated to follow FDA's advice regarding retail food protection programs. The overwhelming majority of these regulatory jurisdictions, however, endorse the concept of a uniform national retail food program. FDA encourages its regional staff to maintain a strong working relationship with our cooperative program partners and to provide them with consultation, training, and technical assistance to enhance the effectiveness of their retail food programs.

The OHFI Deputy Director should closely examine on a case-by-case basis those circumstances that may cause some states in their respective regions not to be receptive to the initiatives outlined in the National Retail Food Program. A meeting with top state officials should be considered by the OII OHFI(Office of Human Food Inspectorate)Deputy Director and State Cooperative Program Director, and the Retail Food Specialist to foster enhanced communication and program implementation. The National Retail Food Steering Committee, the HFP Office of Domestic Programs (ODP),OII Office of Training and Education Development Training(OTED), and the Office of Retail Food Protection (OFRP) are available if further assistance or consultation is needed.

B. Planning Instructions

Regulatory jurisdictions' self-assessments, Retail Food Specialists' consultations, OTED's annual training needs surveys, and field observations are the principal mechanisms by which FDA determines and documents state program priorities.

These activities provide data on (1) the level of consumer protection in each state, and (2) the specific needs of the state program.

FDA bases the allocation of program resources and funding on these activities. The performance indicators for these activities gauge the impact of our program operations. FDA's technical assistance and other program-related activities in each jurisdiction are planned in cooperation with program officials. FDA personnel are to meet with program officials to accomplish this coordination task. FDA's National Retail Food Program Work Plan is designed to support jurisdictions' needs in implementing the Program Standards, training and standardization of their staff, and in addressing program-specific food safety priorities. Hours allotted in the categories of Technical Assistance and Workshops allow flexibility for the Regions to assimilate any unique needs of their jurisdictions into the work plan.

FDA's NRFT implements its initiatives regionally. The Agency's ability to allocate its limited resource capacity in support of each jurisdiction's program needs will be assessed in the context of food safety initiatives contained in the National Retail Food Program and the FDA Retail Food Safety Initiative. Priorities within the work plan are established to achieve both long- and short-term program goals and objectives.

C. Compliance Program Status Reports

At the end of the fourth quarter, the Retail Food Specialists will submit a summary report to the Office of Retail Food Protection (ORFP), concerning the status of regional compliance program operations. ORFP will, in turn provide copies of the summary report to the Office of Compliance and Enforcement (OCE), Compliance Programs and Assignment Branch (CPAB). The report should follow the recommended format provided in the Compliance Program Status Report included as **Attachment A**. The report is extracted from the FACTS. To enable printing of this report, Food Specialists must individually enter their work time at least quarterly using the latest revision of the "Reporting Guidance for National Retail Food Team State Retail Food Team."

The **Attachment A** Compliance Program Status Report is intended to provide regional and headquarters program managers with information regarding program accomplishments.

D. Program Resource Instructions

Retail Food Specialists who have been standardized per the established “FDA Procedures for Standardization of Retail Food Inspection Officers” in the use of the *Food Code* and in the procedures for standardizing state officials will carry out this program. Other Agency personnel who have been standardized by the Retail Food Specialists can be used for program activities to the extent that they have program training and experience.

E. Work Plan Development

The Retail Food Steering Committee will develop a draft of the upcoming fiscal year's work plan by February 15th. The draft work plan will be based on National Retail Food Program priorities obtained from HFP, OII, regulatory jurisdictions, and other sources. The draft work plan will contain on-going annual activities and projected special projects.

Early in the first quarter of the fiscal year, each regional office will conduct a needs inquiry of all state regulatory programs with responsibility for retail food establishments. Information about jurisdictions' needs within the Region that might influence national initiatives or have national application should be forwarded to the Specialists' Co-Team Leaders and/or the National Retail Food Team Steering Committee by January 1 so that those needs may be assessed and assimilated into the National Work Plan draft if appropriate.

A work plan that is organized in priority order and based on existing FTEs will be provided by the Steering Committee. The draft work plan will be sent to the Regional Directors of Cooperative Programs (DCPs) and the Specialists for review and comment by March 1st. The final draft will be sent by the Steering Committee to the program contact, Office of Field Programs by April 1st. The Fields Programs will coordinate HFP/OIFSSP/RFPB review of the proposed draft work plan. The HFP approved work plan will be submitted to the HFP/OCE/DCOA and the OII Field Food Committee for approval no later than June 15th.

PART III - INSPECTATIONAL

General

The performance indicators for this program are designed to directly assess the impact of national food safety initiatives on the reduction of foodborne illness risk factors within the retail food segment of the industry. The Agency's primary retail food safety vision is to prevent problems before they start in a comprehensive and integrated strategy of prevention, intervention, and response. Program objectives supporting this goal include:

1. Improving regulatory retail food program uniformity through the development of a coordinated work plan focused on increasing the number of jurisdictions adhering to the criteria set forth in FDA's *Voluntary National Retail Food Regulatory Program Standards*;
2. Enhancing the technical competence of regulatory food safety professionals through increasing the number of states that have adopted the *FDA Food Code*, conducting *Food Code* standardizations of inspection personnel and providing technical assistance on retail food program issues;
3. Implementing specific food safety and data collection initiatives identified by HFP as national priorities impacting the retail food program; and
4. Providing workshops and training on technical issues impacting food safety and retail food programs.

There are several specific activities that comprise the intervention strategies designed to accomplish these program objectives. The regions have some flexibility to adjust resources among the designated output categories in response to state needs as long as established Agency objectives and priorities for the fiscal year are met.

1. Improving Regulatory Retail Food Program Uniformity

A. Implementation of FDA's Voluntary National Retail Food Regulatory Program Standards

Retail Food Specialists are scheduled to work with jurisdictions that will be conducting self-assessments of their retail food program using the Retail food Program Standards. The purpose of these self-assessments is to determine a jurisdiction's level of adherence to the criteria within the Standards. Each enrolled

jurisdiction should develop strategic plans for addressing retail food program priorities. These jurisdictional strategic plans should be used to identify and address state priorities within the regionally implemented work plan.

FDA maintains a listing of the status of jurisdictions enrolled in the Retail Food Program Standards. This listing is posted at:

<https://www.fda.gov/food/retail-food-protection/voluntary-national-retail-food-regulatory-program-standards>

Enrolled jurisdictions report achievement of Retail Food Program Standards milestones and status updates to their Retail Food Specialists by submitting a completed FDA National Registry Report 3519 and Release Record Agreement – Permission to Publish in National Registry 3520. Each Retail Food Specialist maintains a file containing the submitted Reports 3519 and 3520 for each enrolled jurisdiction within their primary area of responsibility (assigned States).

On a quarterly basis, Retail Food Specialists provide updates to HFP on the status listing of jurisdictions enrolled in the Retail Food Program Standards. The Retail Food Specialist will complete the Regional Program Standards Status Report (Attachment B) for each jurisdiction that has submitted report forms 3519 and 3520 in the previous quarter. Each FDA Region has a designated coordinator charged with sending these reports to the HFP/OIFSSP contact responsible for maintaining the web page listing on the status of jurisdiction enrolled in the Retail Food Program Standards.

B. Coordinating Implementation of Work Plans and Development of Retail Food Protection – State Program and Support Materials

1) National Coordination of Work Plan Implementation.

Consistent with the availability of funds and program priorities, an annual National Retail Food Team work session will be held for all Retail Food Specialists performing work under this compliance program. The purpose of this work session is to coordinate program activities, revise and update program objectives and methods, develop and strategize new program initiatives, and provide current technical training. All specialists are expected to attend as a requirement for continued certification.

The National Retail Food Steering Committee will be charged with the development of the agenda. Retail Food-Cooperative Programs Coordination Staff (RF-CPCS) together with the Office of Domestic Partnerships (ODP), and the Office of Training and Education

Development(OTED) will initiate coordination of plans for each year's annual meeting. Each region or program division will be responsible for funding the participation of its personnel.

- 2) Team Leaders - National Retail Food Steering Committee. The National Retail Food Specialists Team (NRFST) will select two specialists to participate as representatives of OHFI field activities on the National Retail Food Steering Committee. The Team leaders will be responsible for providing a mechanism for Field Specialists' participation in planning, development, and coordination of the retail food program. Selection of Team Leaders shall be conducted in October of each year. The Team Leaders shall serve overlapping two-year terms. One of the Team Leader positions shall be elected in odd numbered years, the other in even numbered years. A Team Leader shall serve a two-year term. Team Leader, if re-elected, may serve another two-year term. After two consecutive two-year terms, a Team Leader shall step down for a minimum of one year before being nominated for another term.
- 3) National Retail Food Team Work Groups. The Steering Committee will identify projects and initiatives that require development to ensure that the Agency has the necessary procedures, guidance documents, standards, etc., in place to support the program. The Field Specialists will be called upon to assist in the development and review of these program materials through participation in work groups. Areas addressed within these working groups include but are not limited to the Program Standards, *Food Code*, Standardization Procedures, Risk Factor Studies, Preparation for Standardization Workshops, HACCP at retail manuals; Specialist's Standardization, CFP issues, and other timely topics as may be identified by the Steering Committee.

C. Conference for Food Protection

Proposed changes to the *Food Code* and the Voluntary National Retail Food Regulatory Program Standards are presented and deliberated at the biennial Conference for Food Protection meeting. Participation by HFP and the Retail Food Specialists is essential to provide supportive documentation for the deliberation of Conference Issues presented during Council meetings and to convey appropriate technical assistance stemming from Conference outcomes. Therefore, participation is required for continued standardization unless resources do not permit Conference attendance. Each Retail Food Specialist should plan to attend and participate in this biennial (held every "even" year) national food safety meeting where all stakeholders come together to deliberate food safety issues of importance and to determine recommendations for improving the *FDA Food Code* and the Retail Food Program Standards.

2. Food Code Adoptions, Standardizations, and Technical Assistance

A. Promotion of Model Codes

The Retail Food Specialists should seek opportunities to promote adoption of uniform statewide food laws and regulations which are equivalent to the current *FDA Food Code* through contact with food program directors, high level agency management, and other top officials in state government.

This may include:

- Serving on special task forces and committees established to prepare and recommend uniform standards for statewide adoption as requested; and
- Contacting each state that does not have uniform requirements for the purpose of promoting the adoption of requirements substantially equivalent to the *FDA Food Code*.

As needed, to track progress made toward widespread adoption of the *FDA Food Code* and conformance with Program Standard No. 1, HFP/ORFP may request that Retail Food Specialists provide updates on jurisdictions efforts to update their statutes, regulations, and ordinances. In addition, each Specialist should complete the Attachment C - "Report of Adoption of Recommended Model Code", Form FDA 2998 as soon as the jurisdictions has completed its adoption process and forward the form and supporting materials to the ORFP. ORFP will compile information received and provide a national status report to the NRFT at least annually.

B. Standardization of State Officials

The Retail Food Specialists should provide orientation activities necessary to prepare new or renewal state designees for standardization and issue certificates as appropriate. This should be accomplished in accordance with the current version of the *FDA Procedures for Standardization of Retail Food Inspection Officers*.

The Retail Food Specialists should submit the following to the state program officials, when the state designee has successfully passed the standardization or restandardization criteria:

- Notification letter that explains the purpose and conditions for standardization or re-standardization

- Certificate - Inspection/Training Officer

Note: The Retail Food Specialists shall submit to HFP/ORFP any changes to the list of standardized state officials on a quarterly basis. Changes can be submitted via e-mail through a direct link at the top and bottom of the listing on the Retail Food Protection webpage. The list may be accessed on the HFP/Office of Retail Food Protection website at:

[Standardization of Retail Food Safety Inspection Personnel | FDA](#)

C. Technical Assistance

The Retail Food Specialists should provide program consultation as requested and act as the liaison between FDA/HFP and the states regarding highly technical issues. These issues may include, but are not limited to, guidance on implementation of the Program Standards, *Food Code* interpretations, recommendations on compliance procedures, industry management training programs, studies and research concerning retail food protection, etc.

The region should provide program consultation to the retail segment of the industry, industry organizations, and professional organizations as appropriate to promote better understanding and implementation of good public health practices. Requests for consultation regarding new or controversial issues should be coordinated with the ORFP.

2. Training Courses, Regional Seminars and Workshops

A. State Training Courses

The Retail Food Specialists and the Directors of Cooperative Programs (DCPs) are the principal liaison between OTED and the states regarding training needs and course priorities. As a part of the Work Plan development to be carried out by regions required under Part II.3.E, regions will discuss with state jurisdictions strategies for short- and long-term training needs. Working in conjunction with OTED, the Specialists should determine if training is needed in support of program goals. Consideration should be given to other factors besides training that may be hampering a given jurisdiction's attainment of its identified goals (e.g., staffing issues, administrative or legislative issues, etc.). These strategy sessions should feed into the annual OTED training needs survey which OTED sends to state

program officials during the second quarter. The OHFI Office Directors, DCPs, Retail Food Specialists, and HFP/ORFP are copied on the training needs survey distribution. States send requests for FDA classroom training courses for the following fiscal year to their regional DCP (or designee). The regional staff should then forward the region's prioritized list of courses to OTED. OTED then selects courses based on priority and resources. The Retail Food Specialists should participate in all pertinent OTED courses held in their assigned states to provide support (instructional, technical and input on local matters) and follow up with individual jurisdictions on issues that may arise from the course.

In addition, Specialists will continually provide program officials updates on the availability of courses that can be accessed through OTED. Program officials will be encouraged to assess the training needs of their staff using the criteria presented in "FDA's Voluntary National Retail Food Regulatory Program Standard #2 - Trained Regulatory Staff." Standard 2 should be used as one of the rationales for prioritizing course selections to fulfill their specific training needs.

B. Annual Multi-State Seminar for State Officials

An annual Regional Food Protection Seminar provides an opportunity for FDA, the state food program directors, and standardized officials from each state to discuss issues of mutual concern.

The seminar should focus on the Program Standards, self-assessments and strategic plans, *Food Code* interpretations, information exchange, new developments, problem solving, and FDA policies and initiatives impacting retail food protection programs. State reports should follow the format of the *FDA's Voluntary National Retail Food Regulatory Program Standards*:

[FDA Issues 2024 Voluntary National Retail Food Regulatory Program Standards | FDA](#)

The Retail Food Specialists and officials from each state should participate in development of the agenda. Use of outside speakers to discuss special problem areas where appropriate is desirable, when appropriate.

Industry officials should be encouraged to participate. The Retail Food Specialists will provide HFP/ORFP with a draft agenda before the seminar to allow HFP/ORFP to coordinate their input and participation in the seminar and to suggest current topics of national concern and interest.

C. Regional Food Protection Seminar Report

Regional Food Protection Seminars may periodically include agenda sessions focused on issues requiring interpretations of the FDA *Food Code*. For such sessions, the Retail Food Specialists will prepare a report to summarize major issues regarding program policy and *Food Code* interpretations discussed at the meeting. The report need not provide detailed information or minutes of all seminar topics and discussions. If questions of interpretation regarding the *Food Code* requirements and published interpretations are raised, these questions and proposed regional responses should be referred to ORFP for review before distribution to seminar participants.

The HFP/ORFP may also issue the seminar questions and answers to other key food officials, if appropriate. HFP/ORFP review and national distribution of the answers will help promote national uniformity.

D. State Workshops

The Retail Food Specialists should conduct workshops as needed for state regulatory officials. These workshops may include in-depth discussion of such topics as the Program Standards, the *Food Code*, Hazard Analysis and Critical Control Point (HACCP) at retail, active managerial control of foodborne illness risk factors, risk-based inspection methods, foodborne illness investigations, plan review, or special processes. It is recommended that only one subject be covered per workshop.

E. Promotion of Industry Management Training and Certification

Training programs should cover the food safety concepts contained in the *Food Code*. Additionally, training should include discussions of such topics as innovative training approaches based on oral culture learner styles and implementation of voluntary food safety management systems designed to achieve active managerial control of foodborne illness risk factors. Co-sponsorship of training programs by industry, educational organizations, and regulatory agencies is encouraged.

In addition, the region should encourage food regulatory authorities and others evaluating credentials for food protection managers to recognize the Conference for Food Protection/ANSI means of accrediting certification programs. This procedure provides a means for universal acceptance of individuals who successfully demonstrate knowledge of food safety. American National Standards Institute (ANSI) accreditation provides officials assurance that food safety certification is based on valid, reliable, and legally defensible criteria. In addition, universal acceptance eliminates the inconvenience and unnecessary expense of

repeating training and testing when managers work across jurisdictional boundaries.

FDA's recommendations pertaining to food protection manager certification may be found in Subpart 2-102 of the *Food Code*, and the related sections of Annex 3 Public Health Reasons/Administrative Guidelines. Information regarding certification programs that ANSI has accredited as meeting Conference for Food Protection standards may be viewed at <http://www.foodprotect.org/> and click on, Food Protection Manager Certification.

4. National Food Safety Priorities at Retail

A. HFP Retail Food Safety Priorities

Time is allotted in the Retail Food Protection Work Plan to accommodate HFP priorities that are adjusted annually in response to national food safety needs and current initiatives. The ORFP will work with the Steering Committee to establish deliverable objectives for each work plan. The Steering Committee will look for opportunities to coordinate the implementation of HFP initiatives in conjunction with previously identified work plan priorities.

B. Counter-Terrorism at Retail Food Initiative

The Agency has identified the possibility that certain vulnerabilities may exist for tampering or terrorist activity in food establishments. Food defense related materials for the retail industry are available at:

1.
 - Guidance for Industry, Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance: [Guidance for Industry: Food Security Preventive Measures Guidance for Retail Food Stores and Food Service Establishments | FDA](#)
2.
 - Food Related Emergency Exercise Bundle (Free-B)
[Food Related Emergency Exercise Bundle \(FREE-B\) | FDA](#)

- ALERT Food Defense Awareness:
[Guidance for Industry and FDA: Letter to Industry, State and Local Food Regulators and Inspectors Regarding Web-based ALERT Training | FDA](#)
- Employee First – Food Defense Awareness for Front-Line Food Industry Workers [Employees FIRST | FDA](#)
- An Introduction to Food Security (defense) Awareness
[An Introduction to Food Security Awareness | FDA](#)
- Carver + Shock Software Tool:
[Strategic Partnership Program Agroterrorism \(SPPA\) Initiative: Second Year Status Report July 2006 - September 2007 | FDA](#)
- HFP – Food Defense Mitigation Strategies Database
[Mitigation Strategies Database | FDA](#)

The National Retail Food Team (NFPT) is charged with disseminating this guidance information via several avenues: educational presentations at regional seminars and workshops; one-on-one visits with the state retail food program managers; and the development and delivery of presentations or video teleconferences for our stakeholders. Additionally, educational materials and a curriculum for incorporation into several ongoing training courses will be developed.

C. Food Processing Techniques, Industry Procedures, or Food Equipment Evaluation

1. Retail Food Specialists should evaluate upon request:
 - a. Food processing techniques or industry procedures – equivalency of food safety to the *Food Code* for alternative or innovative food safety-related procedures. The findings should be based on a scientific analysis or data that the processing method or procedure does not compromise public health and is reasonable for regulatory agencies to evaluate and regulate.
 - b. Food equipment - acceptability of design, construction, or installation when requested by HFP/ORFP, and as deemed necessary following

requests from regulatory agencies, institutions, and industry. The findings should be based on provisions of the *Food Code*. Other resources that should be consulted include American National Standards Institute (ANSI) Food Equipment Standards, and listings of food equipment that has been evaluated and found in conformance by ANSI accredited certifying bodies. These include organizations such as NSF International (NSF LISTINGS - Food Equipment and Related Products, Components and Materials, <http://www.nsf.org>), Underwriters Laboratories (DIRECTORY - Food Service Equipment, <http://www.UL.com>), and Intertek Testing Services, ETL SEMKO ((published yearly), Directory of Listed Powered Products,). <https://www.intertek.com/directories/etl-listed-mark/>

2. Retail Food Specialists should complete an evaluation report:

- a. For food processing techniques or industry procedures Describe the technique or process and the specialist's evaluation of it in a narrative based on the information and appropriate questions found in Annex 2 of "Managing Food Safety: A Regulator's Guide for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections." When applicable, the specialist should follow the pathway in the "Model Flow Process for State Regulators to Address Variances" found in Annex 3-502.11 of the *Food Code*.

B. For food equipment - Complete FDA 2591 found at <http://www.fda.gov/opacom/morechoices/fdaforms/ora.html> after each equipment evaluation. Provide manufacturer's literature, pictures, and other supporting information as appropriate.

PART IV - ANALYTICAL

NOT APPLICABLE.

PART V - REGULATORY/ADMINISTRATIVE FOLLOW-UP

FDA's responsibilities under this Compliance Program consist of advising state program managers on retail food protection matters regarding the preservation and improvement of the public health. No federal regulatory activity is anticipated within the conduct of this Compliance Program. The Agency is available to assist the states upon request or in conjunction with the cooperative working relationships that have been fostered.

PART VI - PROGRAM CONTACTS, REFERENCES AND ATTACHMENTS

1. PROGRAM CONTACTS

A. Human Foods Program (HFP) Contacts

- 1) Direct program-related questions to Kimberly Destromp, Special Assistant HFP/OIFSSP/ORFP at (414) 326-3981 kimberly.destromp@fda.hhs.gov
- 2) Direct technical questions to Chris Smith, Acting Division Director HFP/OIFSSP/ORFP at (404)253-1264 Chris.smith@fda.hhs.gov
- 3) Direct compliance inquiries to HFP/OCE/OCIC/DCC at hfp-oce-inquiries@fda.hhs.gov
- 4) Direct Compliance Program inquiries to Mildred McCray, CSO, HFP/OCE/DCI CPAB at (240)402-2482 mildred.mccray@fda.hhs.gov

B. Office of Domestic Partnership(ODP)

Direct federal-state relations questions to Wendy Campbell, Acting Director HFP/OIFSSP/OPD/DDPI, at 615-310-0483 Wendy.campbell@fda.hhs.gov

C. OTED Contacts

Direct training questions to the Office of Training, Education and Development, Division of Programmatic Training (Human and Animal Food) at OII-OTED-Retail@fda.hhs.gov

2. REFERENCES

- *FDA Food Code*,

<https://www.fda.gov/food/retail-food-protection/fda-food-code>

- *Retail Food Protection Program* – A Cooperative Program web page, model codes,

model code interpretations, retail food safety procedures, and guidance that are pertinent information disseminated by ORFP and the are available on-line at <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/retail-food-protection>

- *Morbidity and Mortality Weekly Report*: CDC Surveillance Summaries. 2025/No.1
- Contributing Factors of Foodborne Illness Outbreaks — National Outbreak Reporting System, United States, 2014–2022 | MMWR
https://www.cdc.gov/mmwr/volumes/74/ss/ss7401a1.htm?s_cid=ss7401a1_w
- CDC. Surveillance for foodborne-disease outbreaks---United States
https://www.cdc.gov/food-safety/php/data-research/foodborne-illness-burden/?CDC_AAref_Val=https://www.cdc.gov/foodborneburden/burden/index.html
- [Foodborne Disease Outbreak Surveillance System | NORS | CDC](#)
- FDA's *Voluntary National Retail Food Regulatory Program Standards* at
<https://www.fda.gov/media/86651/download>
- *A Procedures for Standardization of Retail Food Safety Inspection Officers*, (November 2010 updated version). <https://www.fda.gov/media/86651/download>

3. ATTACHMENTS

- A. Compliance Program Status Report
- B. FDA Program Standards Reporting Form Template
- C. Report of Adoption of the Recommended Model Code

PART VII - CENTER RESPONSIBILITIES

1. PROGRAM SUPPORT

A. Certification of Retail Food Specialists

Each Retail Food Specialist will be evaluated and standardized every three years as established in the *FDA Procedures for Standardization of Retail Food Safety Inspection Officers*. The Specialists are HFP-Standardized every 6 years. In the intermediate three-year period, the Region's Associate Standard, selected by the Regional Director of Cooperative Programs, will complete the Standardization process for each of the Specialists located in that designated Region. For newly-hired Retail Food Specialists, initial standardization is conducted by HFP. Following the initial HFP standardization, for the next three-year standardization cycle, the Region's Associate Standard will conduct the restandardization exercise.

B. Technical Assistance

ORFP is responsible for maintaining, enhancing, and promoting the *FDA's Voluntary National Retail Food Regulatory Program Standards* as the means of uniform implementation of food safety regulations and enforcement. ORFP is responsible for developing and promoting adoption of the *Food Code* and providing interpretations and opinions as necessary to assist the states in implementing the *Food Code*. provides technical consultation to other federal agencies and through the Retail Food Specialists to the field and to states upon request. ORFP standardizes retail food program specialists to ensure uniform interpretation and application of the model code provisions and national program standards.

C. National Retail Food Steering Committee

ORFP will participate as an active member of the Retail Food Steering Committee. The Steering Committee is the forum for discussion and resolution of retail food program implementation issues, annual work plan development, agenda development for specialists' conferences, and the primary liaison vehicle with the Retail Food Specialists Field Team. The Steering Committee provides a vehicle for coordination between OII and HFP on matters pertaining to retail food protection.

D. Publication of Listings

RFCPCS will publish the following at least annually:

- (1) Cumulative listings of confirmed code adoptions by state, tribal, and federal jurisdictions.
- (2) State, Local, Tribal, and Federal Inspection/Training Officers Standardized by the FDA using the FDA *Procedures for Standardization of Retail Food Safety Inspection Officers* (revised December 2009):
[Retail Food Industry/Regulatory Assistance & Training | FDA](#)
- (3) Listing of jurisdictions enrolled in FDA's "Voluntary National Retail Food Regulatory Program Standards.",
[Voluntary National Retail Food Regulatory Program Standards | FDA](#)

2. Compliance Program Evaluation

The Office of Retail Food Protection (ORFP) Staff, will receive, review, and evaluate all field reports.

During the course of this program, but no later than sixty (60) days after final data receipt, ORFP will identify any deficiencies in the conduct of the field operations or program quality to the Office of Integrated Food Safety Systems and Partnerships (OIFSSP) and the Compliance Assignment and Programs Branch (CPAB) so that any necessary corrective action may be initiated.

ORFP, with input from OIFSSP will prepare periodic, formal evaluations of this compliance program.

ATTACHMENT A
COMPLIANCE PROGRAM STATUS REPORT

FY Final By Region	PAC 18002										PAC 18R8 34	Food Defe nse PAC 18R8 45	Actua l Hours Work ed Towa rds WP	Tot al Hou rs in WP	Tot al FT Es in WP	*Act ual Hour s Work ed	Approx. # FTE on Staff (see Notes for explanat ion of fraction s)	Time Obligat ion based on Actual FTEs	Actual Hours Worke d	OTH ER	PA C 180 02	TOT AL HOU RS (18 + Non 18)
	92				96		95				83	86	92	92	Total Hour s in WP	1200 HRS. X # FTE	Time Obligat ion x 100%	Time Obligat ion x 100%	84 TR. RE C.			
	ASSI ST	SPECI AL	SE M	TEA M	CF P	NE W	R E	STA ND	STU DY	WO RK	PR E	DETA IL	PAR T	GEN								
NER																						

FOOD AND DRUG ADMINISTRATION COMPLIANCE PROGRAM GUIDANCE MANUAL

PROGRAM 7318.002

The figure consists of a 4x10 grid of 40 empty white boxes. The grid is divided into four horizontal sections by thick gray bars. The sections are labeled on the left side:

- The top section is labeled "TOTALS".
- The second section is labeled "CER TOTALS".
- The third section is labeled "SER TOTALS".
- The bottom section is labeled "SWR TOTALS".

Each section contains 10 empty boxes, arranged in a 1x10 grid. The boxes are separated by thin vertical lines.

FOOD AND DRUG ADMINISTRATION COMPLIANCE PROGRAM GUIDANCE MANUAL

PROGRAM 7318.002

COMPLIANCE PROGRAM GUIDANCE MANUAL

PROGRAM 7318.002

ATTACHMENT B
Regional Program Standards Status Report

To be completed by HFP/ORFP

Received on: **To be included on the following update:** October January April July

DATE:

TO: TBD

FROM:

Voice:

FAX:

RE: CHANGE REQUEST FOR THE RETAIL FOOD PROGRAM STANDARDS WEB LISTING

- Add new jurisdiction to the list (new enrollment) Change jurisdiction contact information
- Add 1st Self-Assessment completion date and results Add 2nd Self-Assessment completion date and results
- Update the status of Standards met during 1st Self-Assessment period Update the status of Standards met during 2nd Self-Assessment period
(Self-Assessment date does not change)
(Self-Assessment date does not change)
- Add Verification Audit dates to 1st Self-Assessment Add Verification Audit dates to 2nd Self-Assessment period

**FOOD AND DRUG ADMINISTRATION
COMPLIANCE PROGRAM GUIDANCE MANUAL**

PROGRAM 7318.002

Change FDA contact

Other Specify:

Listing should reflect the following corrections:

STATE:

Enrolled Jurisdiction Name	Enrollment Date	Self Assessment Period	Self Assessment Completed	Standards Reported Achieved Based on Self-Assessment									Jurisdiction Contact Name and Phone	FDA Contact			
				Date Last Verified													
				1	2	3	4	5	6	7	8	9					
		1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
		2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Jurisdiction Contact E-mail Address:																	
Web Link to Jurisdiction:																	
Additional Comments:																	

ATTACHMENT C
REPORT OF ADOPTION OF RECOMMENDED MODEL CODE

(To be completed by FDA Field Food Specialist only)

1. ADOPTING GOVERNMENT JURISDICTION

2. ADOPTION

a. TYPE *(Check one)*

STATUTE - ACT OF LEGISLATURE

REGULATION - PROMULGATED BY ADMINISTRATIVE AGENCY UNDER AUTHORITY OF LAW

ORDINANCE ADOPTION BY LOCAL GOVERNMENT

b. FORMAT *(Check one)*

LONG FORM

SHORT FORM *(By reference)*

c. DATE ADOPTED

d. ADOPTING BODY *(State Legislature, PH Council, County Board of Supervisors (Commissioners), City Council, etc.)*

(To be completed by FDA Field Food Specialist only)

3. EFFECTIVE DATE OF ADOPTED CODE

4. AGENCY DESIGNATED TO ASSUME RESPONSIBILITY (*State or Local Department of Health, Agriculture, Consumer Protection, etc.*)

5. DEVIATIONS BETWEEN ADOPTED CODE AND FDA RECOMMENDATION (*Discuss in detail significant differences, if any, between recommended code and adopted code. For State adoptions, attach a copy of the new law/regulations and inspection report form.*)

REPORT OF ADOPTION OF RECOMMENDED MODEL CODE

(To be completed by FDA Field Food Specialist only)

6. COMMENTS

7 EQUIVALENCY (CHOOSE OPTION A OR B)

- A. IN ACCORDANCE WITH THE SELF-ASSESSMENT AND AUDIT CONDUCTED UNDER PROGRAM STANDARD 1, THIS CODE IS CONSIDERED TO BE _____ SUBSTANTIALLY EQUIVALENT _____ NOT SUBSTANTIALLY EQUIVALENT.

- B. NO SELF-ASSESSMENT HAS BEEN CONDUCTED. HOWEVER, USING THE CRITERIA OF 9 OF 11 MODEL CODE INTERVENTIONS AND RISK CONTROLS AT LEAST AS STRINGENT AS THE MODEL AND APPROXIMATELY 95% OF GMP REQUIREMENTS INCLUDED, THE JURISDICTION'S REPRESENTATIVE HAS PORTRAYED TO THE SPECIALIST THAT THIS CODE _____ IS SUBSTANTIALLY EQUIVALENT _____ IS NOT SUBSTANTIALLY EQUIVALENT.

8. SIGNATURE OF FDA FIELD FOOD SPECIALIST

9. DATE