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Harris County Public Health Risk Assessment Procedure

PURPOSE:

This procedure sets a uniform, easy-to-use way to assign and maintain risk codes for the food establishments the Food Safety & Inspection Program (FSIP) regulates.

Risk codes help FSIP plan inspections and put inspection time where food safety risk is highest. FSIP sorts establishments into at least three risk categories and sets inspection frequency from those categories.

This procedure supports the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), specifically Standard 3 (HACCP-Based Inspection Program), Standard 4 (Uniform Inspection Program), and Standard 6 (Compliance and Enforcement).

PROCEDURE STATEMENT:

FSIP assigns risk codes based on what an establishment actually does that affects foodborne illness risk: food preparation steps, time and temperature controls, specialized processes, and populations served. Texas rules require inspection frequency to reflect both risk and past performance, and allow adjustments for events such as compliance history, complaints, and outbreaks.

FSP 2.0 calculates inspection frequency and the next-due date from the assigned risk code. Investigators must verify that the risk code matches observed operations and that the system frequency lines up with that code.

FSIP sets a baseline risk code (Risk Code 1, 2, or 3) from operational characteristics. The baseline is the lowest risk classification an establishment can

hold, and inspection performance does not lower it. Compliance history and performance trends may lead to enhanced oversight, notification, or escalation, but they do not automatically change the baseline. Risk Code 4 is not a baseline code; it is reserved for establishments under active R&E case management.

PROCEDURE ELABORATION:

I. DEFINITIONS:

- A. Active Managerial Control:** The purposeful incorporation of specific actions or procedures by industry management to attain control over foodborne illness risk factors.
- B. Baseline Risk Category:** A classification of 1–3 assigned on inherent operational characteristics (food preparation steps, time/temperature controls, specialized processes, populations served). The baseline is the minimum classification and is not reduced based on inspection performance.
- C. Enhanced Oversight:** Increased inspection frequency, added follow-up, and/or temporary risk code elevation applied when compliance history, repeat patterns, validated complaints, or public health events indicate elevated risk.
- D. Food Preparation Process Types (Field-Use Definitions):** These terms classify establishment operations by the FDA's food preparation process approach, which is based on the number of times food passes through the temperature danger zone (41°F–135°F). Inspection Officers shall document the highest-risk process conducted at the establishment.
 - **No Preparation** — The establishment offers only commercially prepackaged foods; no open-food handling occurs.
 - **Prepare Ready-to-Eat Foods; No-Cook Step (Process 1)** — Open ready-to-eat foods are handled, assembled, or served with no cook step to destroy pathogens; control relies on employee health, no bare-hand contact, and cold holding.
 - **Immediate Service; Cook and Serve (Process 2)** — Raw or ready-to-cook food is cooked to required temperatures and served immediately; food passes through the danger zone once.

- **Same Day Service; Cook, Hot Hold, Serve (Process 2)** — Food is received, stored, prepared, cooked, hot-held, and served the same business day; food passes through the danger zone once.
 - **Complex Preparation; Cook, Cool, Reheat, Hot Hold, Serve (Process 3)** — Food is cooked, cooled, and later reheated and/or hot-held before service; food passes through the danger zone two or more times, presenting elevated risk for spore-forming and toxigenic bacteria
- E. Highly Susceptible Population:** Persons more likely than the general population to experience foodborne disease because they are immunocompromised, older adults in health care or assisted-living facilities, or preschool-age children in custodial care.
- F. Risk Code:** The FSIP risk designation recorded in FSP 2.0 drives system-calculated inspection frequency. FSIP uses four categories, Risk Code 1 through Risk Code 4, to match inspection resources to risk.
- G. Risk Code 4 (R&E Case Status):** A classification reserved only for establishments under active R&E case management. It is not a baseline category; establishments return to baseline once the case closes unless an elevated baseline is formally approved.
- H. Specialized Process/Specialized Processing Methods:** A non-standard method with elevated risk requiring a variance or HACCP approval (e.g., ROP, sprouting, curing, smoking for preservation, acidification, fermentation).
- I. Time/Temperature Control for Safety (TCS) Food:** A food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

II. BACKGROUND:

Food establishments carry different levels of public health risk based on what they do each day, how they handle food, how complex their preparation is, and who they serve. A consistent risk assessment process keeps oversight uniform across the jurisdiction and focuses resources where risk is highest.

State rules require inspection programs to weigh both risk and past performance. FSIP uses risk codes to set baseline inspection frequency and uses compliance history and AMC trends to guide oversight. VNRFRPS expects each jurisdiction to

keep a written, working process for grouping establishments by risk and setting inspection frequency.

III. PROCEDURE:

A. Set the Baseline Risk Code

1. Start a Baseline Risk Assessment during the Application for Initial Inspection. Confirm it when the establishment is approved to operate and placed in Active status in FSP 2.0.
2. Set the Baseline Risk Code (Risk Code 1–3) when the establishment is approved to operate under FSIP oversight.
3. Verify Risk Code accuracy during inspections and escalate when needed.

B. Review the Risk Code After a Significant Operational Change

Complete a Risk Assessment review when food used or food preparation changes, or when other significant changes raise inherent food safety risk, such as:

- Adding or expanding cooling and reheating of TCS foods.
- Adding hot or cold holding of TCS foods beyond the prior scope.
- Adding raw animal food preparation or higher-risk prep steps.
- Adding a specialized process (e.g., ROP, curing, acidification, sprouting), or running one without required approvals.
- Adding service to a highly susceptible population (e.g., childcare, long-term care).
- Major equipment, menu, volume, or process changes that add complexity.

If significant changes raise inherent risk, the baseline may be elevated and becomes the new minimum. It is not lowered later unless the establishment is formally amended and approved at a lower inherent risk level.

C. Annual and Routine Verification

1. Review the establishment's risk assessment at annual renewal to confirm the baseline still reflects approved and observed operations.
2. During routine inspections, verify that the current risk code matches actual operations and that scheduling lines up with the code.
3. When you confirm significant changes, document them in FSP 2.0 and notify Plan Review or an FSIP Supervisor to update the code and scheduling.

4. Only FSIP Leadership and Plan Review may edit risk codes. Investigators verify accuracy and document observations but must not change codes directly.

D. Risk Code 4 and the R&E Bridge

5. Apply Risk Code 4 only when FSIP escalation directs it and the R&E Unit accepts the case. Do not assign it as a baseline code.
6. Hold Risk Code 4 for the duration of active R&E case management so the establishment receives enhanced oversight aligned with case conditions.
7. When the R&E case closes, return the establishment to its documented baseline Risk Code (1–3) unless either of the following applies, in which case the elevated status is documented in FSP 2.0:
 - An elevated baseline is justified by a confirmed operational change and formally approved by FSIP Leadership and Plan Review under this procedure; or
 - The closing Executive Order or EPH Directive imposes continued conditions—in which case the establishment may remain at Risk Code 4 for a defined enhanced-oversight period to verify and ensure compliance with those conditions, until R&E and FSIP Leadership jointly confirm the conditions are met and authorize return to baseline.
8. Coordinate every Risk Code 4 application, retention, and return-to-baseline decision between FSIP Leadership and the R&E unit, and document the basis and approving authority in FSP 2.0.
9. Use AMC trends and compliance history as the main tools for coordinating between FSIP Leadership and the R&E Unit

IV. RESPONSIBILITIES AND PREVENTION:

Investigators: Verify operations, set and document the baseline at approval events, identify and record significant changes in FSP 2.0, and notify Plan Review or a Supervisor when a review is needed.

Supervisors and Plan Review: Review notifications, approve and apply code updates and scheduling, protect documented baselines, and keep application consistent across districts.

Regulatory and Enforcement Unit: Apply and manage Risk Code 4 for establishments under active enforcement and coordinate on case resolution.

Program Management: Monitor risk distribution and inspection completion and maintain guidance and training for uniform decisions.