Public Health Risk Evaluation (PHRE) VS2

***For Internal Use Only – Do Not Distribute to Establishment ***

The PHRE is a decision-making process that is to be used to determine whether the District Office needs to schedule a Food Safety Assessment (FSA).

***References:**

FSIS Directive 5100.4 ***Enforcement, Investigations and Analysis Officers (EIAO) Public Health Risk Evaluation (PHRE) Methodology***

FSIS Directive 5100.1, ***Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment (FSA) Methodology.***

Establishment Information: Good Eats M9999

PHRE1 **Based on the analysis of the PHRE PHIS report (see FSIS Directive 5100.4), can the Agency take a supportable enforcement action immediately?**
NOTE: If enforcement action will be taken, no FSA is necessary.

☐Yes

☒No

PHRE2 **PHRE Decision: Based on the analysis of the PHRE PHIS report (see FSIS Directive 5100.4), will an FSA be initiated?**

☒Yes- If selected, answer the following questions PHRE4

☐No- If selected, answer the following questions PHRE3

☐Not applicable because of enforcement action

PHRE3 **Describe the reason for not initiating the FSA.**

Click here to enter text.

Assessment Plan: An EIAO is to develop an Assessment Plan prior to performing a FSA .

PHRE4 **Based on the analysis of the PHRE PHIS report (see FSIS Directive 5100.4), describe the Assessment Plan for conducting the FSA.**

The Assessment Plan is to include the:

Apparent violations of the statutes – A brief statement of the apparent or possible food safety issue determined through the analysis. The plan is to cite the relevant statutes or regulations and state or paraphrase the language of the statutes or regulations (e.g., 21 U.S.C. 453 (g)(4) and 458 (a)(3), improperly stored poultry products, after transportation in commerce, under insanitary conditions, causing the

products to become adulterated);

Scope of FSA – Briefly state the extent and range of the FSA, such as tools that will initially be used, regulatory issues, food safety issues or other matters, and any possible public health issues or concerns, and

Steps of the assessment – The steps necessary to develop facts and findings and to collect evidence to the apparent or possible food safety issues.

References: FSIS Directive 5100.4 *Enforcement, Investigations and Analysis Officers (EIAO) Public Health Risk Evaluation (PHRE) Methodology

Good Eats (M9999+P9999+V9999) is a small establishment located in Risky, ID. The establishment produces a variety of meat and poultry products under the Raw Non-Intact, Fully Cooked Not Shelf Stable, Heat-Treated Shelf Stable, and Heat Treated Not Fully Cooked Not Shelf Stable HACCP processing categories. The establishment also performs re-packing of fully cooked of raw intact, raw non-intact, fully cooked not shelf stable, and heat treated not fully cooked not shelf stable products that were produced at other federal inspected establishments. The establishment utilizes Alternative 3 to control Listeria monocytogenes in the post lethality environment.

Due to multiple cooling deviations from the stabilization CCP occurring in multiple fully cooked not shelf stable products since April 2018 in which Clostridium perfringens growth was predicted to be greater than 1 log based upon ComBase modeling, there is concern that the establishment's Fully Cooked Not Shelf Stable HACCP system may be inadequate per 9 CFR 417.6 and as a result, products produced may be adulterated per 21 U.S.C. 601(m)(4). Therefore, it is the recommendation of the EIAO that a food safety assessment be performed at the establishment to determine whether the fully cooked not shelf stable HACCP systems utilized at the facility are adequate, as designed and implemented, to control food safety hazards determined likely to occur in the process so that product produced is wholesome, safe, and unadulterated.

A for cause PHRE was performed utilizing PHIS data from 1/1/2018 to 8/7/2018 due to multiple cooling deviations from the stabilization CCP occurring in multiple fully cooked not shelf stable products since April 2018 in which Clostridium perfringens growth was predicted to be greater than 1 log based upon ComBase modeling, there is concern that the establishment's Fully Cooked Not Shelf Stable HACCP system may be inadequate per 9 CFR 417.6 and as a result, products produced may be adulterated per 21 U.S.C. 601(m)(4). During this time, there have been no consumer complaints or recalls at the establishment. There have been no enforcement actions in the last twelve months at the facility. However, PHR noncompliance rate has increased since the March 2018. The PHR noncompliance rate ending 3/31/2018 was .16%. 4/30/2018, the PHR noncompliance rate was 1.02%. 5/30/2018, the PHR noncompliance rate was 2.21%. 6/30/2018, the PHR noncompliance rate was 1.92%. Current PHR noncompliance rate ending 7/31/2018 is 1.31%. In review of the noncompliance reports (NRs) issued at the facility, there was one SPS NR (issued on 2/19/2018), one pre-operational sanitation NR (issued on 3/21/2018), three fully cooked not shelf stable HACCP NRs (issued 4/29, 5/2, and 5/31/2018), and one raw non-intact HACCP NR (issued 7/25/2018). Therefore, it is the issuance of the 4 HACCP NRs that have directly impacted the PHR noncompliance rate at the facility.

In review of the three fully cooked not shelf stable HACCP NRs, two of the NRs document the failure of the establishment to monitor/identify a deviation from the cooling CCP [9 CFR 417.2(c)(4)] and the failure of the establishment to take corrective actions in response to the deviations [9 CFR 417.3(a)]. The third NR documented the failure of the HACCP plan to include monitoring procedures and frequencies for the cooking and cooling CCPs as

required by 9 CFR 417.2(c)(4) and the failure of the establishment to have decision making documents associated with the development of the cooking and cooling CCPs as required by 9 CFR 417.5(a)(2). The repetitive noncompliance with 9 CFR 417.2(c)(4) leads to concerns that the establishment may not be monitoring per their written procedures or that the monitoring procedures and frequency may not be supported per 9 CFR 417.5(a)(2) which in conjunction with the repetitive noncompliance with 9 CFR 417.3 indicates that e fully cooked not shelf stable HACCP system may be inadequate per 9 CFR 417.6 and products produced, therefore, may be adulterated per 21 U.S.C. 601(m)(4).

The raw non-intact HACCP NR that was issued was for the failure of the establishment to document the results of the record review verification task and does not create any concerns as to the adequacy of this HACCP system as this was the only NR documented for this system.

MOIs for this time period document discussions held with the establishment in regard to measures that could be taken to assist in product cooling and noncompliances issued at the facility, corrective actions taken in response to cooling deviations at the establishment, and on-going initial validation being performed at the facility in response to a vulnerability documented in a FSA performed 6/13/2017. One MOI dated 5/7/2018, documents an outreach visit performed by EIAO, Kevin Bacon, in response to cooling deviations at the facility in April 2018. This MOI documents discussions regarding the change in cooling rates that was occurring at the establishment with current cooling rates to 40°F being almost double of what they were prior to April 2018, concerns regarding the varying range of ambient temperatures of the blast chiller, different validated cooling parameters available, and the option to develop customized cooling parameters.

Since April 2018, the establishment has had five deviations from the cooling CCP within the fully cooked not shelf stable HACCP system. Cooling deviations occurred on all three days in which fully cooked pork bellies were produced, one of six production days in which veal demi glaze was produced, and one day in which bone-in fully cooked pork chops were produced. Due to the on-going deviations from the cooling CCP critical limits, there is potential on-going noncompliance with 9 CFR 417.3(a)(3). Preventative measures taken in response to the deviations may not have been implemented or were ineffective. The on-going deviations from the critical limits also could be an indication of potential noncompliance with 9 CFR 417.5(a)(2) and 417.4(a) as the CCP may not be properly supported and/or validated. As a result of the potential noncompliance with 9 CFR 417.3(a), 417.5(a)(2), and 417.4(a), the Fully Cooked Not Shelf Stable HACCP system may be inadequate per 9 CFR 417.6 and products produced may be adulterated per 21 U.S.C. 601(m)(4).

Therefore, the EIAO recommends that an FSA be performed at the establishment. The FSA should focus on the production of fully cooked bone-in pork chops (Fully Cooked Pork Line HACCP plan), fully cooked pork bellies (Fully Cooked Pork Bellies HACCP Plan), and fully cooked veal demi glaze (Fully Cooked Veal Demi Glaze HACCP plan). The FSA should include observations of each process with particular attention to the monitoring of the cooling process, a review of HACCP records to verify corrective actions to deviations were implemented and met all parts of 417.3(a), and a review of the support and validation for these systems. Results should be documented in the General and RTE tools.

PHRE5 **Will sampling be performed as part of the FSA?**

☒No sampling

☐Yes - If selected, answer the following questions PHRE6, PHRE7, PHRE8

☐Not applicable because of enforcement action

PHRE6 **Select the type of FSA sampling.**

☐RLm

☐IVT

☐Incident Investigation Team (IIT)

☐Other, please explain - Click here to enter text.

PHRE7 **Explain Below: (For IIT plan, cite the investigation team members and the target organism. Describe the objective of the IIT, the sampling plan, and the number of samples to be collected.)**
Click here to enter text.

PHRE8 **Describe any additional resources or expertise you will need as part of the FSA.**
Click here to enter text.