

## **03H HEAT TREATED NOT FULLY COOKED, NOT SHELF STABLE**

**G1.** List all HACCP 03H plans, products produced using those plans, CCPs, critical limits, monitoring procedures, and verification procedures associated with those plans using the template provided.

### **GENERAL HAZARD ANALYSIS, FLOW DIAGRAM and HACCP**

**H1.** Are all hazards reasonably likely to occur identified as appropriate? Yes/No

**H2.** Are all decisions made in the Hazard Analysis supported with documentation on file? Yes/No

**H3.** Briefly explain how the answers in H1 and H2 were determined including the names of documents used. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

**H4.** Does the plant use a prerequisite program(s)? Yes/No

**H4a.** If yes to H4, list the names of all the prerequisite programs used as part of 03H and briefly describe the hazards each prerequisite program is preventing, monitoring procedures, and records generated.

**H4b.** Are there any prerequisite programs lacking adequate supporting documentation that the hazard is not likely to occur? Yes/No

**H4c.** Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision, and the reasoning why these prerequisite program(s) lack adequate support and how this may effect the production of safe product.

**H4d.** If yes to H4, with the records reviewed, has the plant had a deviation from compliance with the prerequisite program? Yes/No

**H4e.** If yes to H4d, did it constitute a trend, did the plant reassess? Yes/No

**H4e.** Is the establishment monitoring and keeping adequate records for each of the prerequisite programs? Yes/No

**H4f.** Describe any additional findings regarding prerequisite programs and briefly describe your analysis of how the prerequisite programs impact the food safety system.

**H5.** Are all steps in the process(s) included in the flow diagram? Yes/No

**H6.** Briefly discuss any regulatory noncompliance associated with the flow diagram. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

**H7.** Does the HACCP plan(s) adequately address each of the hazards that appear reasonably likely to occur based on the hazard analysis(s)? Yes/No

**H7a.** Briefly discuss any hazards that are not adequately addressed and the thought process behind the conclusion. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

**H8.** Based on the questions in FSIS Directive 5100.1, answer the following series of questions to determine if the design of the HACCP plan meets all requirements of 9 CFR 417.

**H8a.** Does the HACCP plan list the monitoring procedures and frequencies used to monitor each of the CCPs to ensure compliance with the critical limits? Yes/No

**H8a1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8b.** Are the monitoring procedures being performed as described in the HACCP plan? Yes/No

**H8b1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8c.** Are the monitoring procedures being performed at the frequencies specified for the CCPs listed in the HACCP plan? Yes/No

**H8c1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8d.** Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments? Yes/No

**H8d1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8e.** Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions? Yes/No

**H8e1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8f.** Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)? Yes/No

**H8f1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8g.** Does the HACCP plan list product sampling as a verification activity? Yes/No

**H8g1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8h.** Are process-monitoring instrument calibration activities conducted as per the HACCP plan? Yes/No

**H8h1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8i.** Are direct observation verification activities conducted as per the HACCP plan? Yes/No

**H8i1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8j.** Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?  
Yes/No

**H8j1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8k.** Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP? Yes/No

**H8k1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8l.** Do the records contain actual values and observations obtained during monitoring? Yes/No

**H8l1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8m.** Does the establishment have the supporting documentation for the initial validation including any cooking instructions? Yes/No

**H8m1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8n.** Does the establishment have the decisionmaking documents associated with the selection of each CCP?  
Yes/No

**H8n1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8o.** Do the documents explain why the establishment selected that location for the CCP? Yes/No

**H8o1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8p.** Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards? Yes/No

**H8p1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8q.** Does the establishment have scientific, technical, or regulatory support for the critical limit? Yes/No

**H8q1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8r.** Does the support appear credible? Yes/No

**H8r1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8s.** Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan? Yes/No

**H8s1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8t.** Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done? Yes/No

**H8t1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8u.** If the establishment has supporting documents for these decisions, does the documentation support the decisions? Yes/No

**H8u1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8v.** Do the records document the monitoring of CCPs and their critical limits? Yes/No

**H8v1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8w.** Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan? Yes/No

**H8w1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8x.** Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date the record was made? Yes/No

**H8x1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8y.** Are the verification procedures and results of those procedures documented? Yes/No

**H8y1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8z.** Is the time recorded when the verification activity was performed? Yes/No

**H8z1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8aa.** Does the record contain the date the record was made? Yes/No

**H8aa1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8bb.** Are the process-monitoring calibration procedures and results being recorded? Yes/No

**H8bb1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8cc.** Was each entry on the record made at the time the event occurred? Yes/No

**H8cc1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8dd.** Does each entry include the time? Yes/No

**H8dd1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8ee.** Was each entry on the record signed or initialed by the establishment employee making the entry? Yes/No

**H8ee1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8ee.** Are the records being maintained for the required amount of time, e.g., 1 year for slaughter and refrigerated products and 2 years for frozen, preserved, or shelf-stable products? Yes/No

**H8ee1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8ff.** Are the records kept on-site for 6 months? Yes/No

**H8ff1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8gg.** If the records are stored off-site after 6 months, can they be retrieved in 24 hours? Yes/No

**H8gg1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8hh.** Has the establishment reviewed the records associated with the production of the product, prior to shipment? Yes/No

**H8hh1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8ii.** Has a reassessment been conducted to meet the annual reassessment requirement? Yes/No

**H8ii1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8jj.** Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis? Yes/No

**H8jj1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8kk.** Has change occurred that could affect the hazard analysis or HACCP plan? Yes/No

**H8kk1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8ll.** Did the establishment reassess? Yes/No

**H8ll1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**H8mm.** If the reassessment revealed that the HACCP plan no longer meets regulatory requirements, was the HACCP plan modified immediately? Yes/No

**H8mm1.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

### **Validation and Support**

**VS1.** Does the establishment have adequate support that products produced under 03H are NRTE vs. RTE? Yes/No

**VS1a.** Please provide information supporting your decision in VS1.

**VS2.** Does the establishment have adequately cooling procedures in their HACCP plan(s) to address biological food safety hazards? Yes/No

**VS2a.** Are the cooling procedures validated? Yes/No

**VS2b.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**VS3.** Do all products produced under 03H contain special handling instructions per 9 CFR 317.2(k) or 381.125(a) (i.e Keep refrigerated, Keep Frozen, etc.)? Yes/ No

**VS3a.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**VS4.** Are all products produced under 03H properly labeled with safe handling instructions per 9 CFR 317.2(l) and 9 CFR 381.125(b) (i.e. cooking instructions, for further process, etc.)? Yes/No

**VS4a.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

**VS5.** Do all products not labeled for further processing, contain validated cooking instructions? Yes/No

**VS5a.** Has the establishment identified the critical variables (e.g., time, temperature, cooking method, etc.) used in the validation? Yes/No

**VS5b.** If the critical values have been identified for the cooking instructions, are they being applied on the label in a similar manner? Yes/No

**VS5c.** Is the product or product formulation used in the validation the same as or similar to the product or product formulation for which the establishment is using the cooking instructions for? Yes/No

**VS5d.** Are the cooking instructions on the label as described in the validation with regards to equipment and procedures? Yes/No

**VS5e.** If the critical variables, product formulation, procedure or equipment used in the cooking instructions are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are sufficient? Yes/No

**VS5f.** If the establishment did not conduct additional validation, did it provide any rationale to explain why the cooking instructions are effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different? Yes/No

**VS5g.** Did the establishment initially test for the adequacy of the cooking instructions to produce a safe product? Yes/No

**VS5h.** Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision in VS5-VS5g.

**G2.** Describe any additional findings (positive and negative) associated with the 03H plans not addressed in the previous questions.

**G3.** Analysis: Please describe your recommendation for the HACCP 03H plans and describe the above collected data supporting those recommendations. Include in your discussion how the findings impact the establishment's ability to meet the requirements of the FMIA/PPIA and that impact on food safety.