

7130.3InspectionProc-CookedSausage21192

7130.3

OPI: S&T/PPID

INSPECTION PROCEDURE FOR FAT AND ADDED WATER IN COOKED
SAUSAGE

I. PURPOSE

This directive provides Inspection Program employees with methods for monitoring the levels of fat and added water in finished cooked sausage products and for verifying that these levels are within the limits that have been set by regulation. The inspection procedure prescribed by this directive is to be followed only in official establishments for which a quality control program for fat and added water in cooked sausage has not been approved by FSIS. This directive is not applicable to Import Inspection employees.

II. CANCELLATIONS

MPI Manual, Section 18.24 (e) through (g).

III. {RESERVED}

IV. REFERENCES

9 CFR Sections 318.9, 319.140, 319.180, 319.181, 319.182, and 320.6. MPI Manual, Section 18.24, except paragraphs (e) through (g) which are cancelled; Sections 23.2, 23.3, 23.4, except paragraphs (a)(2) and (b)(2) which have been cancelled; and Section 23.5.

FSIS Directive 5400.1, Rev. 1, dated 5/3/90

FSIS Directive 7140.2, dated 9/10/90

FSIS Directive 7220.1, Rev. 2, dated 8/24/ami, braunschweiger, and Polish sausage, were unaffected by the rules change; there is no limit on the fat content of such products but the added-water maximum is 10 percent (9 CFR 319.140, 9 CFR 319.182).

VII. POLICY

A. As required by MPI regulations, FSIS employees monitor the processing of cooked sausage products to assure that no adulterated or misbranded products are produced. Finished product is randomly sampled for laboratory analysis according to a schedule generated by the PBIS.

B. Ranges of analytical results for samples, called "zones," are used to allow for inherent variations in the manufacturing process, finished product sampling, and analytical error. The FSIS Statistics and Data Systems Division derived the zones in Tables I and II from statistical analysis of production data.

C. Procedures for verifying the fat content of cooked sausage products, as set forth in this directive, are not followed when an approved Nutrition Labeling Verification (NLV) procedure is used in the establishment for labels that bear fat content claims. Instead, compliance with the fat content

restriction is monitored through the approved NLV procedure; the %Fat limits in Table I do not apply. However, the inspection monitoring procedures do apply with respect to the 40%-of-product maximum allowed combination of fat and added water and the %Fat plus %Added Water sample limits from Table I.

D. The procedures in this directive for verifying fat and added water in cooked sausage products are not followed when an FSIS-approved QC program, establishing alternative means of monitoring fat and added water in sausage products, is operated in the establishment. Inspection Program employees are to follow the procedures for monitoring the approved QC program in lieu of the procedures in this directive. (An exception to this instruction is described in FSIS Directive 8830.1, Initiation of a Progressive Enforcement Action.)

E. All samples drawn from FSIS retained lots must be analyzed either by an FSIS laboratory or, at the expense of the establishment operator, by an accredited laboratory.

VIII. DEFINITIONS

A. Compliance Factor. A product attribute that is measured against a regulatory standard. The regulatory standard for cooked sausage products subject to MPI regulation 319.140 is percent added water. The regulatory standards for cooked sausage products subject to MPI regulations 319.180 and 319.181 are percentage fat and combined percentage of fat and added water.

B. Lot. A single shift's production of cooked sausage product of the same size and type container/casing and processed under one basic formula or method of preparation. For example, franks, bologna, and knockwurst produced in a single shift are three separate lots. In addition, pork and beef franks, beef franks and beef franks with by products are also separate lots. However, 10-to-a-pound or 8-to-a-pound wieners packed in 1 lb, 2-lb, or 3-lb containers would be considered the same lot.

C. Lot Inspection. Finished product testing of a production lot(s) for laboratory analysis. Acceptance of the lot, which represents the manufacturing process, is determined using either normal acceptance criteria or tightened acceptance criteria, depending upon sample results.

D. Normal Sampling. Sampling at a rate that is generated by the PBIS.

E. Plant-Requested Sampling - Sampled Lot. The drawing of 30 individual samples from a previously sampled lot that has failed the

acceptance criteria in tables III, IV or V.

F. Plant-Requested Sampling - Unsampled Lot. Sampling from an unsampled lot of product from which a sample has not been physically drawn (unsampled lot - see definition) but which is subject to the same standard as other lots produced on the same shift, including at least one lot that has failed the acceptance criteria listed in table III. or IV.

G. Sample. Three separate 1-pound units of unpackaged product randomly selected from different portions of a single lot. Under normal sampling or tightened sampling, the sample represents all lots of product subject to the same standard as specified in 9 CFR 319 Subpart G produced during the same shift. For example, if the sample was taken from a lot of franks, that sample would also represent lots of bologna and knockwurst produced during that same shift.

H. Sampled Lot. A lot of product, subject to the same standard as product in other lots produced on the same shift, from which a sample has been physically drawn.

I. Shift. The FSIS approved establishment hours of operation as specified on the plant profile, FSIS form 8810-1.

J. Tightened Sampling. Sampling on a per-shift basis that is initiated by the Inspection Program employee according to the decision guidelines in tables III. and IV.

K. Unsampled Lot A lot of product, subject to the same standard as product in other lots produced on the same shift, from which a sample has not been physically drawn.

L. Zones. Under lot inspection, sample results are categorized by statistically derived zones A, B, C, D, or E, to reflect increasing amounts of variation and possible cause for action. The combined fat-plus-added-water sample-result zones are defined in table I. and the added-water sample-result zones are defined in table II.

IX. RESPONSIBILITIES

A. Establishment responsibilities:

Controlling the process through process monitoring and assuring that the finished product is in compliance with the requirements of MPI regulations 318.2 and 318.7 (9 CFR 318.2 and 318.7) and, where applicable, 319.140, 319.180, 319.181, or 319.182 (9 CFR 319.140, 180, 181, 182).

B. Inspection Program employee responsibilities:

1. Monitoring the compliance of cooked sausage products with the regulatory limitations on fat and added-water content by taking samples of the products. The sampling schedule is generated by the PBIS (reference

FSIS Directive 8800.1).

2. Maintaining records of samples and laboratory results.

3. Taking appropriate action when sample results indicate noncompliance with the regulations as specified in tables III. and IV.

X. DIRECTIONS FOR SAMPLING AND RECORDING RESULTS

A. General Procedure.

1. The Inspection Program employee randomly selects and submits a sample to an FSIS laboratory or designated accredited laboratory to be analyzed for fat and total moisture. Added water is then determined in accordance with FSIS Directive 7140.2. The results are used in deciding whether the processing controls in the establishment are effective and whether product is consistently in compliance with regulatory requirements for fat and added-water content. The Inspection Program employee determines what action to take by noting the zone in table I. or II. in which the sample result falls and the results of previous sample analyses and by consulting tables III. or IV.

2. Under normal sampling, the task frequency is determined by the prevailing rules of PBIS. Normal acceptance criteria are used for the first sample and continued when the sample results meet the acceptance criteria in table III.

3. Under tightened sampling, the task frequency is on a per shift basis and is initiated by the Inspection Program employee. The tightened acceptance criteria in tables IV. are used until the establishment management has demonstrated control of the process, as indicated by sample results.

4. Cooked sausages with the fat-plus-added-water limit and those with only an added-water limit are identified as separate product categories in Process 11 of the ISG.

5. If a product is under tightened sampling and acceptance criteria for a certain compliance factor and the PBIS schedules a sample collection for that product, the Inspection Program employee collects a sample from a lot, requests that tests be conducted for all compliance factors, and uses the normal acceptance criteria for the compliance factor not under tightened sampling and acceptance criteria. If all compliance factors for the product are under tightened sampling and acceptance criteria, the scheduled task should not be performed and task code (J) marked on the schedule.

B. Directions for Sampling.

The designated Inspection Program Employee:

1. Determines whether the establishment is under normal or tightened sampling.
2. Randomly selects three 1-pound units from different portions of a single lot of unpackaged finished product. (Do not composite the sample.)
3. Indicates product name, lot number, establishment number, production date, and sample number on each sample container/bag. Writes on each container/bag either "1 of 3," "2 of 3," or "3 of 3," as appropriate.
4. Completes FSIS Form 10,600-1 for each sample (of three 1-pound sample units). (See MPI Manual Part 23.4.)
5. Prepares sample for shipment. (See MPI Manual Part 23.5 and FSIS Directives 7355.1, 10,140.1, and 10,600.1).

XI. COMPLIANCE DETERMINATION AND RECOMMENDED ACTION

The Inspection Program employee:

A. Records sample results and enters an "x" in the block for the appropriate zone on the Scoresheet For Record of Compliance with Cooked Sausage Requirements, FSIS Form 7130-3 (see Attachment), maintaining a separate sheet for each compliance factor: fat plus added water, fat, and added water. Sample result zones and limits are shown in tables I. and II.

B. Follows the Decision Guidelines, tables III. and IV.

1. Normal acceptance criteria (table III.) are used for the first sample and continue to be used as long as sample results meet the criteria.

2. Tightened acceptance criteria for shift production (table IV.) are used when sample results do not meet normal acceptance criteria and continue to be used until the results justify a resumption of normal sampling and acceptance criteria. Product produced after the shift for which samples have been drawn but before plant management is notified that the rate of sampling is to be changed from normal to tightened is to be tested and disposed of according to the criteria in table IV. or V. However, the results of the tests on this product shall not be used to determine whether to switch from tightened to normal sampling.

3. After plant management has been informed that tightened sampling is in effect, normal sampling will be resumed if the test results for each sample from four consecutive shifts are in zone A.

4. Plant management, after being notified of the use of tightened inspection criteria, may elect to have each lot tested for compliance factors. Each such lot is to be disposed of in accordance with the criteria in table V. If the results of all lots in the shift are in

zone A, the inspector records on FSIS Form 7130-3 the test result that is closest to the regulatory standard for the compliance factor in question. If the test results fall in two or more zones, then the inspector records the most severe non-complying product result on FSIS Form 7130-3. If each sample lot result from four consecutive shifts is in zone A, normal sampling is resumed.

5. Each of the compliance factors is monitored separately. For example, a product under tightened sampling and acceptance criteria for fat may be under normal sampling and acceptance criteria for fat plus added water.

6. Under normal or tightened sampling, the laboratory results of the sampled lot represents all of the unsampled lots of similar product, as specified in 9 CFR 319 Subpart G, produced in the same shift. Any action taken on the sampled lot (other than resampling) also applies to the unsampled lots of similar product from that shift.

XII. PLANT-REQUESTED SAMPLING PROCEDURES

Retained lots that cannot be released under the previously described procedures may be sampled at the request of the establishment management.

A. Unsampled Lots. Follow instructions for sampling in X.B.2 - 5. Use the criteria in table IV. or V. The processor may have a sample drawn from each of the unsampled lots produced in a shift or the processor may group all the unsampled lots into one lot and have a single sample drawn from that lot.

B. Sampled Lots. The Inspection Program employee, or a designated plant employee under Program supervision, randomly selects 30 individual 1-pound samples from each failed lot. Each sample is analyzed individually. Use the criteria in table VI. The average of the 30 individual sample results cannot exceed the Zone A maximum and no individual result may be in Zone E.

W. S. Horne
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Attachments

- 1- Table I, Sample Result Zones for Cooked Sausage Products; and Table II, Sample Result Zones for Percent Added Water
- 2- Table III, Decision Guideline (Normal Acceptance Criteria)
- 3- Table IV, Decision Guideline (Tightened Acceptance Criteria - Shift Production)
- 4- Table V, Decision Guideline (Tightened Acceptance Criteria - Plant-Requested Sampling - Unsampled Lots); and Table VI, Decision Guideline (Tightened Acceptance Criteria - Plant-Requested Sampling - Sampled)

Lots)

5- FSIS Form 7130-3, Scoresheet for Record of Compliance with Cooked Sausage Requirements (REFERENCE HARD COPY OF THIS DIRECTIVE)

6- Cooked Sausage Sampling Flow Chart (REFERENCE HARD COPY OF THIS DIRECTIVE)

TABLE I

SAMPLE RESULT ZONES FOR COOKED SAUSAGE PRODUCTS
(Normal & Tightened Criteria)

Zone	%Fat	%Fat Plus %Added Water
A	30.0 - under	40.0 - under
B	30.1 - 30.6	40.1 - 41.2
C	30.7 - 31.1	41.3 - 42.3
D	31.2 - 31.6	42.4 - 43.4
E	31.7 - over	43.5 - over

TABLE II

SAMPLE RESULT ZONES FOR PERCENT ADDED WATER
(Normal & Tightened Criteria)

Zone	%Added Water
A	10.0 - under
B	10.1 - 11.0
C	11.1 - 12.0
D	12.1 - 13.0
E	13.1 - over

TABLE III

DECISION GUIDELINE
(Normal Acceptance Criteria)

IF LAB RESULT IS...

THEN...

o Zone A, B or nonconsecutive C, but less than 7 consecutive results above Zone A criteria (Table III).

o Shift's production is acceptable. Continue normal sampling under PBIS using normal acceptance

o Seventh consecutive result above

o Permit the shift's production

Zone A, second consecutive Zone C,
or one in Zone D

represented by the sample to move
freely, and

- o Initiate tightened sampling and
take official control action,
pending sample results, on
subsequent shifts' production,

and

- o Go to tightened acceptance criteria
(Table IV).

o Zone E

- o Take official control action on
available entire shift's produc-
tion represented by the sample,
and

- o Initiate corrective action
according to Directive 8820.1,
and

- o Initiate tightened sampling and
take official control action,
pending sample results on
subsequent shifts' production,
and

- o Go to tightened acceptance
criteria (Table IV).

TABLE IV

DECISION GUIDELINE
Tightened Acceptance Criteria
Shift Production

IF LAB RESULT IS...

THEN...

o Fourth Consecutive Zone A

- o Shift's production is accept-
able. Permit product represented
by the sample to move freely, and
- o Return to normal sampling and
normal acceptance criteria (Table
III).

o Zone A (other than fourth consecu-
tive Zone A) or Zone B

- o Shift's production is accept-
able. Permit product represented

- by the sample to move freely, and
- o Continue tightened sampling and official control action, pending sample results, on subsequent shifts' production, and
- o Continue under tightened acceptance criteria

o Zone C, D, or E

o Continue official control action on entire shift's production represented by the sample, and

o Initiate Corrective Action according to Directive 8820.1, and

o Continue tightened sampling and official control action, pending sample results, on subsequent shifts' production, and

o Continue under tightened acceptance criteria.

TABLE V

DECISION GUIDELINE
Tightened Acceptance Criteria
Plant-Requested Sampling - Unsampled Lots

IF LAB RESULT IS...

THEN...

o Zone A

o Lot is acceptable. Permit product represented by the sample to move freely.

o Other than Zone A

o Continue official control action and corrective action on lot represented by the sample

TABLE VI

DECISION GUIDELINE
Tightened Acceptance Criteria
Plant-Requested Sampling - Sampled Lots

IF

THEN...

o The average of the 30 individual sample results does not exceed Zone A and

o Lot is acceptable. Permit product represented by the sample to move freely.

o No individual result is in Zone E

o The average of the 30 individual sample results exceeds Zone A or lot represented by the sample.
o An individual sample result exceeds Zone E

o Continue official control action and corrective action on