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OPI: SCI/FIAD

PUMPED BACON SAMPLING PROGRAM--NITROSAMINE ANALYSIS

PART ONE---BASIC PROVISIONS

I. PURPOSE

This directive prescribes procedures to inspection personnel for pumped bacon sampling for nitrosamine analysis. It provides for separate sampling programs for establishments continuing to process pumped bacon under the traditional method as prescribed in Section 318.7(b)(1) and (2) of the MPI regulations and for those establishments electing to process pumped bacon under one of the reduced nitrite methods as prescribed in Section 318.7(b)(3) and (4) of the MPI regulations.

II. CANCELLATION

FSIS Directive 10,520.1, dated 5-16-86.

III. REASON FOR REISSUANCE

To include the provisions of Section 318.7(b)(3) and (4) of the MPI regulations which describe the reduced nitrite processing methods and the sample collection procedures for pumped bacon. This directive has been revised in its entirety.

IV. REFERENCES

MPI Regulations sections 318.4, 318.7, and 318.21. FSIS Directive 10,600.1, Sample Shipment Procedures, dated 10-6-83. Chemistry Laboratory Guidebook.

V. ABBREVIATIONS AND FORMS

The following will appear in their shortened form in this directive:

FSIS Food Safety and Inspection Service  
IIC Inspector in Charge  
PQC Partial Quality Control

FSIS Form 10,000-2 Laboratory Report (formerly FSIS Form 6000-1)

FSIS Form 10,520-1 Pumped Bacon Sampling Program--  
Nitrosamine Analysis Process Chart

FSIS Form 10,530-1 Domestic Requested Residue Sampling  
Program (formerly FSIS Form 6000-2)

VI. DEFINITIONS

A. Traditional Processing Method. A method for processing pumped bacon where sodium nitrite is used at 120 parts per million (ppm) ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing), and sodium ascorbate or sodium erythorbate is used at 550 ppm.

B. Reduced Nitrite Processing Methods. Optional methods for processing pumped bacon provided the establishment has an FSIS approved PQC program and:

1. Sodium nitrite is used at 100 ppm ingoing (potassium nitrite at 123 ppm ingoing) and sodium ascorbate or sodium erythorbate is used at 550 ppm, or;

2. Sodium nitrite is used at a predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm), and sodium ascorbate or sodium erythorbate is used at 550 ppm; sucrose or other similar fermentable carbohydrate is added at not less than 0.7 percent; and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii*, or other bacteria demonstrated to be equally effective in preventing the formation of botulinum toxin, is used at a level sufficient for this purpose.

C. Presumptive Positive Results. A result obtained by Thermal Energy Analyzer analysis which indicates that a confirmable level of nitrosamines might be present in monitoring, retention, or alternate process procedure samples.

D. Monitoring Phase. The sampling and analysis program for establishments which prepare pumped bacon using a currently approved process procedure. During this phase, pumped bacon moves unrestricted in commerce.

E. Confirmation Phase for Traditional Processing Method. The sampling and analysis program for establishments which have experienced a presumptive positive result for a monitoring phase sample and do not immediately change to an approved alternate process procedure. During this phase, pumped bacon moves unrestricted in commerce.

F. Confirmation Phase for Reduced Nitrite Processing Methods. The sampling and analysis program for establishments producing bacon under the reduced nitrite processing methods that have experienced a presumptive positive result for a monitoring phase sample. The confirmation phase sample is taken from the production run following corrective action to the PQC program. During this phase, pumped bacon moves unrestricted in commerce.

G. Retention Phase. The sampling and analysis program for establishments which have experienced a confirmable level of nitrosamines for a confirmation phase sample. During this phase, all pumped bacon in the establishment is retained. Operators of such establishments are provided the option to sample each retained production lot, divert retained bacon for use as a material in products where nitrosamine formation will not occur, or destroy all retained bacon.

H. Acceptable Curing Solution. The ingredient makeup of a pumped bacon curing solution which has been determined by FSIS to satisfy the critical ingredient (i.e., nitrite, ascorbate) restrictions of Section 318.7 of the MPI regulations.

I. Process Procedure. A detailed writeup, such as FSIS Form 10,520-1 (Attachment 2), provided by establishment operators and filed in the assigned inspector's office for:

1. Any process procedure approved by FSIS for an establishment which has never experienced a confirmable level of nitrosamines in any phase, or;

2. Any currently approved alternate process procedure (See subparagraph VI. J.).

NOTE: Each process procedure should be identified distinctly in a manner acceptable to the IIC and the Circuit Supervisor.

J. Approved Alternate Process Procedure. A procedure previously approved by FSIS which satisfies the requirement that five consecutive production lot samples are analyzed by an FSIS accredited laboratory or an FSIS laboratory and presumptive positive results are not indicated in any of the five consecutive lot samples.

K. Production Lot. One shift's production of pumped bacon.

L. FSIS Accredited Laboratory. A non-Federal analytical laboratory that has met the requirements for accreditation specified in Section 318.21 of the MPI regulations and, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. For the pumped bacon sampling program, only alternate process procedure or retention phase samples may be analyzed by an accredited laboratory and they are analyzed at the expense of the establishment.

## VII. POLICY

### A. Application.

This directive and the referenced regulations, section 318.7, apply only to bacon prepared from pork bellies which are pumped with curing solutions. Establishments which do not manufacture pumped bacon (e.g., only slice and package bacon) are not involved in this sampling program.

This directive modifies the sample size for both the traditional and the reduced nitrite processing procedures. The change in sample size provides a more precise estimate of the average nitrosamine level resulting from a traditionally processed lot, i.e., a better indication of the overall nitrosamine level which might result when bacon obtained throughout a lot is cooked. This directive also provides for a single, uniform sampling regime for FSIS inspectors to carry out. The presumptive positive results and the confirmable level of nitrosamines are the same, regardless of the production

method. The sampling regime described in this directive does not preclude the inspector's responsibility to take samples and retain product if the inspector believes that product is adulterated.

#### B. Bacon Sampling Program.

In accordance with section 318.7(b)(2) of the MPI regulations, FSIS conducts a bacon sampling program to obtain information concerning the performance of pumped bacon manufactured under the requirements of Section 318.7(b)(1). The sampling program consists of three phases--monitoring, confirmation, and retention. Before a curing solution's use may be permitted, its formulation must be identified by FSIS as an "acceptable curing solution" for the preparation of pumped bacon. Pumped bacon is prepared in accordance with an establishment's acceptable process procedure(s) (See subparagraph VI. I.). In the event that identification of the procedure(s) and products are not maintained during preparation, processing, storage, and sampling, action based on sample results, as described in Part Three, will apply to all product in the establishment regardless of the procedure used to prepare it. Precooking at the establishment does not exempt the bacon from the requirements of the regulations. Cover pickle containing nitrate and/or nitrite is not permitted in the preparation of pumped bellies.

#### C. Additional Processing Methods.

1. Section 318.7(b)(3) of the MPI regulations describes additional processing methods for pumped bacon (See subparagraph VI. B.). These optional methods permit a lower level of nitrite to be used in conjunction with an approved PQC program which, as in other PQC programs, becomes the primary method for process control, and thus compliance with regulatory requirements.

2. FSIS conducts an alternative sampling plan for establishments electing to use lower levels of nitrite in conjunction with an approved PQC program. The basic purpose of this sampling plan is to determine whether establishments are maintaining control over the process to avoid conditions which can lead to nitrosamine formation. This alternative system is a national monitoring plan used as a tool with other inplant inspections to provide assurance that the PQC programs are functioning and that the products produced are in compliance with the regulations.

### PART TWO----SAMPLE COLLECTION/ANALYTICAL PROCEDURES

#### I. SAMPLE COLLECTION PROCEDURES

A. General Instructions. The FSIS headquarters determines when inspectors collect and submit monitoring phase samples. FSIS Form 10,530-1 (Attachment 3) is sent to an inspector for use in sample collection under the monitoring phase at the time a sample is requested. Regional offices and the headquarters' staff coordinate confirmation and retention phase and alternate process procedure samples, which are assigned a project number to be used during sample collection and reporting of results. The FSIS Form 10,000-2 (Attachment 1) is used for sample collections in the confirmation and

retention phases, and for alternate process procedure samples . Inspectors shall prepare an FSIS Form 10,000-2 for each production lot of bacon sampled, i.e., five forms for an alternate process procedure, one form for a confirmation sample, and three forms for each retained production lot. Forms accompanying samples should be protected in plastic bags.

#### B. Specific Instructions.

1. During the monitoring phase, when an establishment is not producing bacon on the collection date designated on the FSIS Form 10,530-1, determine the next production date and contact the regional office for instructions .

2. Update the regional office through channels concerning establishments that are starting or discontinuing pumped bacon operations.

3. Inform establishment management immediately prior to collecting samples and give them the opportunity to participate in companion sample collections.

4. Collect "regular" sliced bacon. DO NOT sample bacon that is labeled "thick sliced" or "thin sliced. " Labeling such as "sliced bacon" or "regular sliced bacon" is considered regular sliced bacon regardless of number of slices per pound. Where regular sliced bacon is not prepared, collect samples of slab bacon .

5. If slab bacon must be used for sampling, the selected portion (s) shall have the rind removed and be sliced (approximately 10 slices per inch). If slicing is not possible, send the whole selected portion (s) to the laboratory. DO NOT cut the slab portion(s) into pieces.

6. On the bottom of the FSIS Form 10,530-1, or in block 15 of FSIS Form 10, 000-2, list the product name and ingredients, the inplant control number of the approved process procedure the sample represents, the production date, and the production lot from which it was collected.

7. Where possible, indicate on the FSIS Form 10,000-2 or the FSIS Form 10,530-1 whether the sample bacon originated from fresh or frozen bellies.

#### II. SAMPLE SIZE

The following instructions apply to both traditional bacon processing and reduced nitrite processing.

##### A. Monitoring and Confirmation Phases.

1. A sample shall consist of five 1-pound packages of regular sliced bacon or that equivalent of bulk sliced bacon. Collect the sample from five random selections spaced approximately equally throughout the production lot.

2. When only slab bacon is available, select a 1-1/2-pound portion

from  
interv throughout the lot, for an overall total of 7-1/2 pounds to be

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#### B. Retention Phase.

When the sampling option is selected:

1. For each identifiable production lot, randomly choose three  
hout the lot, and  
from each of these locations, randomly collect a sample cons  
pound  
Identify each separate sample  
lot numb  
slicing date on each FSIS Form 10,000-2.

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e

2. When only slab bacon is available, randomly choose three separate  
ons, from approximately equal segments throughout the lot, and fro  
each location collect 2-1/2 pounds of bacon from each of two adjacent slabs,  
con. Identify each five pound unit as follows:  
Project  
location  
10,000-2.

h

m

#### C. Alternate Process Procedure.

1. From each of five consecutive normal size production lots, randomly  
n, for an overall  
total 25 pounds. Each package shall be collected at approximately equal  
e intervals throughout the lot's production. Separately package each S  
pound sample, representing each consecutive normal size production lot, and  
label  
for each lot.

e

2. When only slab bacon is available, collect a sample weighing 7-1/2  
lots. Each sample  
unit  
randomly selected at approxima  
each sample unit consecutively A through E, clearly identifying the packaging

s

### III. SAMPLE SUBMISSION PROCEDURES

#### A. Preshipping Instructions.

1. Completely chill all samples. DO NOT freeze samples. Place  
e containers with  
the chilled bacon just prior to mailing the sample.

2. Insert the sample in the shipping carton with as few folds a

possible as the bacon must be separated and pan fried for testing.

3. Package the sample to be sent "priority mail." Where sample containers are not readily available, collect the sample as specified and hold under refrigeration and official security. Immediately contact the regional office, through channels, to provide sample containers.

B. Shipping Instructions (Refer also to FSIS Directive 10,600.1).

1. Send monitoring and confirmation samples to the FSIS laboratory in Athens, Georgia, at the following address:

USDA, FSIS, Science  
Eastern Laboratory  
College Station Road  
P.O. Box 6085  
Athens, GA 30604

2. Send retention phase samples to the FSIS laboratory in Athens, Georgia, at the above address, except in those situations where establishment management requests and the FSIS headquarters approves submittal to an accredited laboratory.

3. Send alternate process procedure samples to an accredited laboratory except in those situations where establishment management requests and the FSIS headquarters approves submittal to the FSIS laboratory in Athens, Georgia, at the above address. Whenever an accredited laboratory is used, samples must be received in good condition by the accredited laboratory. If the set is received in an unacceptable condition for analysis, the laboratory shall discard the set and the inspector shall repeat the sample collection procedures. Accredited laboratories shall use the same analytical procedures approved for the FSIS laboratory.

#### IV. ANALYTICAL TESTS

##### A. Nitrosamine Methods.

The laboratory may use any analytical method which has undergone a collaborative or validation study and is approved by the Chemistry Division, Science Program, FSIS.

##### B. Other Tests.

In addition to the nitrosamine analysis, the laboratory shall perform pH, residual nitrite, and yield of cooked bacon on each sample.

NOTE: Samples must be fried, and the yield of cooked bacon and the analyses for pH and residual nitrite performed on the 21st day after bacon slicing (or packaging for slab bacon). The nitrosamine analysis shall be performed as soon as possible after the sample has been fried. An establishment may request that the FSIS laboratory analyze retained samples earlier than 21 days after slicing (or packaging), but the analytical results found will determine product compliance. However, an establishment may request an accredited laboratory to analyze the samples any number of times up until the 21st day after slicing (or packaging).

V. ANALYTICAL RESULTS

Any samples obtained by Thermal Energy Analyzer analysis which Presumptive s that a confirmable level of nitrosamines is likely to be present being considered positive. Each nitrosamine is treated separately; there is

B. Confirmable Level of Nitrosamines.

Any confirmation than 10 parts per billion (ppb) producing regulations. r I

PART THREE---ACTIONS BASED ON SAMPLE RESULTS

I. SAMPLING PHASES FOR ESTABLISHMENTS USING TRADITIONAL

A. Monitoring Phase.

Whenever a monitoring phase sample analysis identifies a presumptive positive into the confirmation phase and to collect a confirmation sample.

If the establishment has an approved and tested alternate process (See Part One, subparagraph VI. J.) and it elects to immediately change to the alternate process procedure, a confirmation sample is not required and the establishment may remain in the monitoring phase.

B. Confirmation Phase.

1. Whenever confirmation sample findings indicate nonconfirmable the establishment to the monitoring phase.

2. If confirmation sample findings indicate confirmed levels of nitrosamines, retention phase (see Part One, subparagraph VI. G.). e

NOTE: Confirmation samples are analyzed 21 days after collection. During this procedure, the confirmation sample will not be analyzed and will be permitted to return to the monitoring phase using the new alternate process procedure. s

C. Retention Phase.



1. Whenever the results of all three parts of a retained lot sample indicate no presumptive positive results, the inspector shall release the particular lot of product represented by that sample.

2. If the results of any part of a retained lot sample indicate presumptive positive results, the entire lot fails. The IIC shall notify establishment management of the findings and inform them of available options for disposition of the particular lot. It is to be disposed of in a manner to assure that nitrosamines will not form when the product is cooked. Such disposal may include incorporation of the uncooked bacon as an ingredient of another meat food product, provided it is processed for eating in a manner to preclude the formation of nitrosamines.

3. The inspector may return the establishment to the monitoring phase for new productions only when an approved and tested alternate process procedure (See Part One, subparagraph VI. J.) is available and the FSIS headquarters' staff concurs with this action.

#### D. Alternate Process Procedure.

1. Whenever the results of all five consecutive production lot samples indicate no presumptive positive results, the alternate process procedure shall be deemed "approved" and may be used in normal production. The establishment shall be returned to the monitoring phase.

2. If the results of any of the five consecutive production lot samples indicate presumptive positive results, the alternate process procedure shall be disapproved. The IIC shall notify establishment management of the findings.

## II. SAMPLING PHASES FOR ESTABLISHMENTS PRODUCING BACON UNDER REDUCED NITRITE PROCESSING OPTIONS

### A. Monitoring Phase.

1. Using the same analytical procedures as used for monitoring phase samples of bacon prepared using traditional processing methods, when a presumptive positive result is found for a monitoring sample, the inspector shall notify the establishment management who is responsible for initiating investigations on the possible causes of the elevated value and for identifying corrective actions.

2. The inspector may observe or participate in the activity and shall determine whether the investigation and action appear adequate and ensure that the PQC program is revised, if warranted.

### B. Confirmation Phase.

1. The IIC shall collect another sample (as described in Part Two, subparagraph I. A.) from the next production run following the corrective actions and send it to the FSIS laboratory in Athens, Georgia, for analysis.

2. If nitrosamine findings on this sample are below 10 ppb (shown in Part Two, Subparagraph V. B.), the establishment shall remain in the sampling program for reduced nitrite processing options.

3. If nitrosamine findings in this sample are equal to or above this action level, the inspector shall notify the establishment management who must select one of the following options:

a. An approved and tested alternate procedure for the traditional processing method, or;

b. An approved and tested PQC procedure for the reduced nitrite processing options which is different than the one used up to this time.

4. If the establishment chooses option a. above, it surrenders the approved PQC program for the reduced nitrite processing options under the provisions of Section 318.4(g)(1) of the MPI regulations. The establishment shall be switched to the sampling program for traditional processing methods. In order to make that switch, the inspector shall immediately notify the regional office through channels. The regional office shall then notify the Food Ingredient Assessment Division, Science Program. If, at a later date, the establishment wishes to return to the reduced nitrite processing options, it shall contact the Processed Products Inspection Division, Technical Services, FSIS.

5. If the establishment chooses option b. above, the PQC program remains in effect and the establishment remains in the sampling program for reduced nitrite processing options.

C. Retention Phase.

If the establishment has neither a previously approved and tested alternate procedure (option a.) nor a previously approved and tested PQC procedure (option b.), or if the establishment does not choose either option a. or b., it shall be placed in the retention phase as described in Part Three, subparagraph I. C. Further instructions to the inspector shall come through the Processing Operations Staff, Inspection Management Program, Meat and Poultry Inspection Operations.

Lester Crawford  
Administrator

Attachments

- 1 FSIS Form 10,000-2, Laboratory Report (See paper copy of this directive.)
- 2 FSIS Form 10,520-1, Pumped Bacon Sampling Program--Nitrosame Analysis Process Chart (See paper copy of this directive.)
- 3 FSIS Form 10,530-1, Domestic Requested Residue Sample Program (See paper copy of this directive.)