Mr. Philip Derfler  
Assistant Administrator  
Office of Policy, Program and Employee Development  
Food Safety and Inspection Service  
Room 350 Administration Building  
U.S. Department of Agriculture  
Washington, D.C. 20250-3700


Dear Mr. Derfler:

This letter requests that the Food Safety and Inspection Service (FSIS or the agency) take action to update the inspection procedures related to the evaluation of meat trimmings currently defined by MPI Bulletin 83-53, *Trimmings from Meat*, 10/12/83, by publishing a new Directive. This request is on behalf of the members of the American Meat Institute (AMI). AMI is the nation’s oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products. Our member companies account for more than 90 percent of U.S. output of these products.

This letter provides background information on meat trimmings, the MPI Bulletin, current practices in industry regarding production of meat trimmings, analytical and statistical approaches to ascertaining the % lean/% fat in meat trimmings, validation and verification of production practices, and a recommendation for the new Directive.

**BACKGROUND**

MPI Bulletin 83-53 was written in 1983 and describes meat trimmings as either meat or fat with visible lean tissue. These trimmings are used in the preparation of products subject to the maximum fat contents provided for in 9 CFR 319 as well as the Nutritional Labeling in 9 CFR 317 Subpart B. MPI Bulletin 83-53 defines *meat trimmings* as trimmings with “visible lean tissue” and *meat fat* as trimmings containing less than 12% trimmable lean. The procedure for evaluating trimmings and discriminating between these two categories needs updating because of better analytical and statistical control procedures that improve the discrimination. Changes in processing procedures and customer specifications that have occurred since the bulletin was written also affect the applicability of the current MPI Bulletin 83-53.

Blended trimmings are sold for further processing (e.g., hot dog manufacturing) according to the fat/lean ratio specified for the intended use. MPI Bulletin 83-53 provides that meat trimmings
below 12% lean are considered as “beef or pork fat with visible lean;” and industry follows this
guidance currently when labeling trimmings. In nearly all instances, meat trimmings are blended
to meet customer specifications (i.e., requirements for trimmings that will be used in further
processing). Larger pieces that meet the MPI Bulletin 83-53 “presence of lean” visual
requirement entering the blender may be broken down in the blending process, resulting in
smaller pieces with no visible lean, and thus, when inspected individually out of the blended
mixture, result in a “failed test” according to MPI Bulletin 83-53. With today’s production
processes, measures are in place (e.g., in-line and finished product analysis for fat/lean ratios) to
more accurately define lean content and to satisfy the expectations of further processors.

The current application of the MPI Bulletin 83-53 by FSIS inspection staff both at production
facilities and customers’ receiving facilities has led to labeling blended meat trimmings as meat
fat because one or two pieces in the blend have no visible lean. The recommended new
Directive would permit the use of visual inspection of trimmings; but it eliminates “single piece
judgments on the presence of lean,” and allows the use of more systematic inspection techniques
in combination with statistical data analysis to substantiate that meat trimmings meet the 12%
lean limit.

CURRENT PRACTICES

As per your request, the following outlines the current practices associated with the sampling and
testing of raw materials (i.e., unblended meat trimmings used to produce blended trimmings with
a specified % lean content) and blended trimmings. If you require additional information
regarding these current practices, please request that information.

Sampling and Testing Standard Operating Procedures

Establishments that produce meat trimmings use a standard operating procedure (SOP) such as
the following generic example:

**Purpose:** Procedure describes method to compute % lean/% fat in meat trimmings.

**Scope:** All products labeled as *beef fat with visible lean, pork fat with visible lean, beef fat
trimmings, pork fat trimmings, beef lean trimmings, or pork lean trimmings.*

**Responsibility:** Plant Operations has the responsibility to ensure that all meat trimmings
meet regulatory requirements. Quality Assurance has responsibility to monitor, verify and
document compliance, and to validate the SOP methodologies described herein.

**Procedure:** Meat Trimmings and Blended Meat Trimmings

- Raw materials (i.e., unblended meat trimmings) used to make blended trimmings (i.e.,
  final products produced to meet internal and external customer specifications) are
  sampled to assess the level of lean
- Unblended meat trimmings are sampled at a frequency (based on the specific process
  characteristics) to ensure that the manufacturing process is stable and capable according
to statistical process control. Raw materials used to produce blended trimmings are
  sampled and tested on a lot basis, with the data used for statistical process control
  analysis for verification that any variation is associated only with common causes, not
  assignable causes, and thus, within expected statistical variation (see *statistical analysis
  of data* section below).
- Blended trimmings are produced to meet an internal or external customer specification,
generally for use in formulated products. A representative sample (e.g., 10 pounds) of
blended trimmings is taken for each lot of blended trimmings. The sample is taken at the exit of the blender, with the data (lean measurement test results) used for statistical process control analysis for verification that any variation is associated only with common causes, not assignable causes, and thus, within expected statistical variation (see statistical analysis of data section below).

- All trimmings, whether as raw materials or blended trimmings, will meet the 12% lean requirement, as defined through visual and/or analytical testing to be labeled as meat trimmings.
- The procedures used to determine the lean content are given below.

**Methodologies Used for Assessing Fat Level**

There are two methods to determine the %fat/%lean composition of blended or non-blended meat trimmings.

**Visual and Physical Separation Assessment**: Visual examination enables one to gauge the approximate proportion of pieces of trim that have visible lean tissue. Only by examining the entire container (i.e., 100% inspection of a combo bin) piece-by-piece, and physically separating the lean tissue from the fat tissue, will a determination on the % lean be possible and accurate. Trimmings, whether unblended or blended, are sorted into lean and fat pieces as well as into a collection of pieces that contain both lean and fat. Those pieces with both lean and fat are separated using a knife, with fat and lean being separated into their distinctive collections of fat only and lean only. When completed, weighing the separate collections allows the determination of % lean on a total weight basis.

If a statistical relationship is established between a sampling and visual/physical separation regime (e.g., examination of a portion of a container of raw materials or blended trimmings to characterize the entire container of raw materials or lot of blended trimmings), then such a statistically-based protocol can be used to estimate the lean content of the entire container or lot of trimmings or blended trimmings. Validation of this relationship requires preliminary sampling and testing by visual and physical separation of a portion of a container in comparison to the entire container. Repeated comparisons (e.g., 10 containers of trimmings) would provide the necessary correlation data to substantiate that measurement of a portion of the container accurately reflects the % lean content of the entire container (e.g., Figure 1).

![Figure 1. Comparison of Visual/Physical Separation Analysis of Trimmings](image-url)
Chemical/Spectral Measurement of Lean Content: An alternative to the visual and physical separation method described above is a statistically-based sampling (e.g., coring and mixing) and testing method (e.g., in-line X-ray, Anyl-Ray, wet chemistry) to ascertain the % lean/% fat content of raw materials (i.e., unblended trimmings) or blended meat trimmings. Statistical process control charts of the % lean/% fat data are calculated based on an initial set of 30 data points, and updated as each new % lean/% fat data point is determined through chemical/spectral testing. Each specified % lean product would have its unique statistical process control chart.

To establish the sample-to-sample variation, 10 samples of blended trimmings will be taken for a single lot over the production time, and tested for lean content. To establish the reproducibility of the chemical/spectral method, multiple measurements of lean content will be made on the same sample as part of the validation.

**Validation and Verification Practices**

Validation of the measurement protocol used to determine the % lean/% fat content of meat trimmings (unblended and blended) is done before using the method for routine production. Validation of the visual method and the chemical/spectral method could be done simultaneously by sampling, conducting a 100% visual and physical separation analysis of the trimmings, conducting a visual and physical separation analysis on sub-samples of the entire container (to generate the correlation explained above and exemplified by Figure 1) and by conducting the chemical/spectral measurement on at least three analytical units taken from the same sample. This validation allows a calculation of the correlation between methods. For example, the correlation between the visual and chemical/spectral analyses is exemplified by Figure 2.

![Figure 2. visual vs. chemical analysis](image)

Quarterly verification of the sampling and testing program determines whether the establishment is manufacturing meat trimmings or blended meat trimmings using a statistically-controlled process. This verification includes the verification that the SOPs are followed for the sampling and testing program, that equipment is calibrated according to the prescribed schedule, and that the chemical/spectral analytical method is checked through the use of controls and blanks.

**Statistical Analysis of Data**

Each targeted % lean production process, designed to meet internal or external customer specifications, has an associated statistical process control chart (exemplified by Figure 3) that
describes the variation around the targeted value. The variation, or process control, is defined by the upper and lower control limits that characterize normal, or common cause variation associated with the measurement of % lean. By establishing the control chart, and continuously updating the chart as new data are generated, it is possible to determine whether data points fall within normal variation or whether there is an assignable cause for variation that indicates the process is out of control. When an out of control event occurs, the control chart identifies this event, and the establishment can begin the investigation to determine the assignable cause, make an adjustment in the process, measure the % lean, and evaluate whether the process has returned to an in-control state.

The use of the process control chart prevents unnecessary adjustments to the process based on a single measurement value; such adjustments only increase variation. Adjustments to the process are made only in response to assignable causes. The control charts also serve to communicate to the inspection staff the status of the production of products targeted for specific % lean contents. The inspection staff need only to review the process control charts, along with the verification activities described previously in this report, to verify that the % lean content of blended trimmings meet the regulatory requirements for labeling products appropriately as meat trimmings.

**Customer specifications**

Internal and external customers specify what % lean content need to be generated for meat trimmings used in subsequent manufacturing. Many customers require analytical test results to substantiate the % lean content in blended trimmings sent to and received by their establishments. The use of statistical control charts enables both suppliers and customers to verify that meat trimmings meet the specifications for the products.
THE REQUEST

AMI is requesting that FSIS update the procedures for use by field inspection staff to evaluate the lean status of trimmings based on better science in use today to measure and discriminate the lean content of trimmings. For establishments choosing not to use improved scientific methods to determine the lean content of meat trimmings, the traditional physical and visual assessment can be used. This traditional method, however, needs to be modified to allow measurement of a sample size that prevents the categorization of an entire blended lot or combo of raw materials based on finding a single piece of trim that contains “no visible lean.” Visual examination will enable one to gauge the approximate proportion of pieces of trim that have visible lean tissue. Absence of finding such a piece in a small sample of trimmings does not guarantee such a piece might not be present, even in a combo where the overall lean content is 20%. Only by examining the entire container (i.e., 100% inspection of a container of trimmings) piece-by-piece, and physically separating the lean tissue from the fat tissue, will a determination on the % lean be accurate. Such a visual discrimination process is very time consuming, whether done by the establishment or by the inspection staff. Such a time consuming tasks means that the number of verification checks that can realistically be done is limited.

An alternative to the visual and physical separation method is the use of scientific analytical methods and statistical data analysis to substantiate that the process of discrimination is under statistical control. Under these circumstances, the FSIS verification activity becomes one of verifying that the establishment has a sampling (e.g., coring and mixing) and testing method (e.g., in-line X-ray, Anyl-Ray, wet chemistry) to ascertain the % lean content of meat trimmings, whether before or after blending. Statistical process control charts of the % lean data can be used to illustrate that the process is in control. Verification of the sampling and testing program can determine whether the establishment is manufacturing meat trimmings or blended meat trimmings using a statistically-controlled process. Verifying that the SOPs are followed for sampling and testing, that equipment is calibrated, and that the method is checked through the use of controls and blanks will ensure that meat trimmings (≥12% lean) and fat trimmings (<12%) are properly labeled.

Please let me know if and when you act upon this request. If you determine not to act upon this request, please notify me, and if possible provide your rationale. Thank you in advance.
DRAFT PROPOSAL FOR NEW DIRECTIVE

DIRECTIVE ______________ : ASSESSMENT OF TRIMMINGS FROM MEAT

I. PURPOSE

The purpose of this Directive is to clarify procedures used to assess the lean content of trimmings from meat destined for further processing.

II. CANCELLATION

This Directive replaces MPI Bulletin 83-53, Trimmings from Meat, 10/12/83.

III. REASON FOR ISSUANCE

Manufacturing and analytical processes for trimmings from meat, and customer specifications and uses for these trimmings, have changed since 1983. The Directive addresses new assessment procedures to categorize trimmings from meat based on lean content.

IV. REFERENCES

FSIS MPI Bulletin 83-53  Trimmings from Meat, 10/12/83

V. BACKGROUND

MPI Bulletin 83-53 was written in 1983 and describes meat trimmings as either meat or fat with visible lean tissue. These trimmings are used in the preparation of products subject to the maximum fat contents provided for in 9 CFR 319 as well as the Nutritional Labeling in 9 CFR 317 Subpart B. MPI Bulletin 83-53 defines meat trimmings as trimmings with “visible lean tissue” and meat fat as trimmings containing less than 12% trimmable lean. Changes in processing procedures, use of statistical process control to manage data, and customer specifications that have occurred since the bulletin was written affect the application of MPI Bulletin 83-53.

In all cases, blended trimmings are sold for further processing (e.g., hot dog manufacturing) according to the fat/lean ratio specified for the intended use. MPI Bulletin 83-53 provides that meat trimmings below 12% lean are considered as “beef or pork fat with visible lean;” and industry follows this guidance currently when labeling trimmings. In nearly all instances, meat trimmings are blended to meet customer specifications (i.e., requirements for trimmings that will be used in further processing). Larger pieces that meet the MPI Bulletin 83-53 “presence of lean” visual requirement entering the blender may be broken down in the blending process, resulting in smaller pieces with no visible lean, and thus, when inspected individually out of the blended mixture, result in a “failed test” according to MPI Bulletin 83-53. With today’s production processes, measures are in place (e.g., in-line and finished product analysis for fat/lean ratios) to more accurately define lean content and to satisfy the expectations of further processors.

The current application of the MPI Bulletin 83-53 by FSIS inspection staff both at production facilities and customers’ receiving facilities has led to labeling blended meat trimmings as meat
fat because one or two pieces in the blend have no visible lean. This Directive permits the use of visual inspection of trimmings; but it eliminates “single piece judgments on the presence of lean,” and allows the use of more systematic inspection techniques in combination with statistical data analysis to substantiate that meat trimmings meet the 12% lean limit.

VI. GENERAL PROCEDURES FOR ASSESSMENT OF MEAT TRIMMINGS

A. VISUAL AND PHYSICAL SEPARATION ASSESSMENT

There are several ways to determine the %fat/%lean composition of blended or non-blended meat trimmings. Visual examination will enable one to gauge the approximate proportion of pieces of trim that have visible lean tissue. However, only by examining the entire container (i.e., 100% inspection of a container of trimmings) piece-by-piece, and physically separating the lean tissue from the fat tissue, will a determination on the % lean be possible and accurate. However, it is no longer appropriate to determine that an entire container of meat trimming must be considered as fat trimmings solely based on finding pieces of trim with no discernible lean tissue, i.e., the entire contents of the container must be considered collectively.

B. ALTERNATIVE METHODS OF ASSESSMENT

An alternative to the visual and physical separation method described above will be to verify that the establishment has a sampling (e.g., coring and mixing) and testing method (e.g., in-line X-ray, Anyl-Ray, wet chemistry) to ascertain the approximate % lean/% fat content of trim as it is manufactured and sold as a blend, or as pre-blended meat trimmings. Statistical process control charts of the % lean/% fat data can be used to illustrate that the process is in control. Verification of the sampling and testing program can determine whether the establishment is manufacturing meat trimmings or blended meat trimmings using a statistically-controlled process. Verifying that the Standard Operating Procedures are followed for the sampling and testing, that equipment is calibrated, that the method is checked through the use of controls and blanks, and that periodic validation of the method is done will ensure that meat trimmings (≥12% lean) and fat trimmings (<12%) are properly labeled.

VII. LABELING

Blended and unblended meat trimmings are to be labeled as fat (<12% lean) or lean (≥12% lean). Suitable names for fat trimmings include “Beef fat with visible lean,” “Pork fat with visible lean,” “Beef fat trimmings,” or “Pork fat trimmings.” Lean trimmings will be labeled as “Beef lean trimmings” or “Pork lean trimmings.”

VIII. GUIDANCE

For additional information contact the Technical Service Center.