

OTHER CONSUMER PROTECTIONS TECHNICAL PAPER

Current Procedures for Addressing OCP Concerns

FSIS' OCP activities can be grouped under seven headings:

- (1) Food Standards/Food Labeling
- (2) Food Labeling - Net Weight
- (3) Food Labeling - Species Identification
- (4) Food Labeling - Nutrition Labeling
- (5) Economic Adulteration of Raw Product
- (6) Raw Product Quality After Slaughter (Reinspection)
- (7) Carcass Sorting

A. Food Standards/Food Labeling

The food standards enforced by FSIS include several different types of requirements. There are minimum limits for the meat or poultry content, e.g., beef stew must contain a minimum of 25% beef. There are limits for fat, added water, and protein content, e.g., fresh pork sausage can contain no more than 50% fat. There are required ingredients, e.g., Italian sausage must contain fennel or anise or both. There are requirements for maximum weight gain during processing, e.g., corned beef brisket can weigh no more than 20% over the weight of the fresh uncured brisket. Finally, there are processing specifications,

e.g., barbecued meat must be prepared using dry heat from burning wood or coals therefrom.

FSIS engages in a variety of activities to ensure that industry complies with food standards. These activities include label review and approval, laboratory analyses of product samples, and in-plant inspection activities. The type of activity FSIS employs is determined by the nature of the requirement. The prior label approval system has provided a check to ensure that the formula for a particular product is consistent with the standard. In-plant inspection activities are conducted to determine whether the approved formula is being followed, to determine whether weight gain limits are met, and to determine whether the right label is being applied to the product. Laboratory analyses are conducted on product samples to check for compliance with fat, water, and protein limits and to verify that an establishment's QC program related to fat, water, or protein limits is working.

Food labeling is included under the same heading as food standards in this document because the activities employed to ensure that labeling is truthful are the same as those used to ensure compliance with food standards. For example, analyzing a ground beef sample for fat can determine both whether there is compliance with the food standard (maximum

of 30 percent), and whether a labeling claim of 20 percent fat is truthful. Observing the formulation of a product during production can determine both whether there is compliance with a minimum meat requirement, and whether the list of ingredients is accurate. Thus, label review and approval, in-plant inspection procedures, and laboratory analyses are described in the discussion that follows as they apply both to food standards and to labeling requirements.

1. Label Review and Approval

FSIS conducts a prior approval program for labels used on federally inspected meat products and poultry products. Under this program, an application that includes the label, formulation information, a description of processing procedures that is sufficient to support the accuracy of the label, and handling information is submitted to FSIS. The application must identify any product quality or nutrient content claims that will be included on the label and must include information to support the accuracy of such claims.

FSIS reviews the application to ensure that the labeling complies with all Federal regulations and labeling policies. For example, FSIS reviews the formula to ensure that it is consistent with existing product standards, e.g., the formula for a meat stew would have to meet the

standard's requirement for not less than 25 percent meat of the species named on the label, computed on the weight of the fresh meat. Formulas are reviewed and measured against both food standards published as regulations and all informal interpretive standards in the Standards and Labeling Policy Book.

If the label is going to include a production claim, e.g., a claim related to how the animals or birds used in the product were raised or fed, the application would have to include a description of the process or procedures used to ensure the validity of the claim. This policy was reiterated in the FSIS Federal Register Notice, "Certified Organic By" Labeling on Meat and Poultry Products (64 FR 17607).

FSIS significantly changed the label approval process in a final rule published on December 29, 1995 (60 FR 6744). This rule expanded the category of generically approved labels. Generically approved labels can be used on meat products and poultry products without individual review by FSIS before use. Today, the majority of new labels are generically approved. FSIS is conducting an audit of how well generic approval is working. The preamble to the 1995 final rule stated that the Agency would consider expanding

the generic approval system after conducting such an assessment of the system.

FSIS is examining the continuing need for a prior approval system. Like any other review or inspection activity, the prior approval system does not guarantee 100 percent compliance. In the early 1990's, FSIS conducted studies to examine the effectiveness of the prior label review system. The data it collected showed that more than 25 percent of the incoming applications had one or more discrepancies (any variation from an existing regulation or policy). In FY 1991, 13.6 percent of applications were returned with a rejection letter. Another similar number (estimated 14 percent) were corrected during the review process and then passed for approval. Thus, during the early 1990's, an estimated 27.6 percent of applications arrived at the Agency with some deficiency. While these findings could be used to support the need for FSIS review and approval, the deficiency rate of 27.6 percent indicates that many establishments were leaving it to FSIS to sort acceptable labels from unacceptable labels, and to correct or provide guidance for correcting the labels. FSIS is continuing to evaluate the need for prior label approval and will consider proper roles and responsibilities when

considering alternative verification and enforcement activities.

2. In-Plant Inspection Tasks

In-plant inspection tasks employed to ensure compliance with food standards or food labeling requirements complement the prior label approval system. The prior label approval system provides a correct label, and the in-plant tasks of FSIS inspection program personnel ensure that production practices are consistent with the label. With these complementary activities, neither the FSIS in-plant inspection personnel nor industry personnel have had to become totally familiar with the extensive and complex requirements imposed by food standards and food labeling regulations.

The following discussion of FSIS in-plant inspection activities refers to PBIS tasks and data collected before the implementation of Hazard Analysis and Critical Control Point (HACCP) requirements. Thus, this discussion refers entirely to inspection tasks identified in the Inspection System Guide (ISG), which is the list of inspection tasks that will be applied prior to HACCP implementation. For establishments under HACCP, FSIS has restructured the ISG tasks into new procedures and activities published as the Inspection System Procedures (ISP). The tasks described

here will, however, continue to be used in almost 3,000 very small establishments until January 2000.

The purpose of this discussion is to provide an overview of how FSIS has traditionally approached the consumer protection issues of misbranding and economic adulteration. The transition from the ISG to the ISP does not fundamentally alter that approach. There have been some changes, however. The number of activities identified in the ISP is far lower than the number of tasks included in the ISG. The ISG was designed to capture all tasks related to an ongoing inspection program. Not all ISG tasks, however, were based on regulations. Some ISG tasks were based on FSIS Directives, Policy Memoranda, and the Standards and Labeling Policy Book. The ISP has been structured to define activities conducted to measure compliance with regulatory requirements. Thus, only ISG tasks that correspond to an existing regulatory requirement are incorporated into the ISP framework.

The ISG includes many tasks that are conducted primarily to ensure that products are correctly formulated and labeled appropriately. As an example, Task 06A01a2 instructs inspection program personnel to examine a sausage product during formulation to check for correct ingredients and accurate weights of ingredients. This task is intended

to determine whether the actual production practice is consistent with the list of ingredients on the approved label, and whether the ingredients are used in portions consistent with the approved order of predominance. This task is scheduled three times per week in establishments producing sausage. Prior to HACCP implementation, the task was performed approximately 120,000 times per year. Inspection program personnel documented some problem or finding approximately once every 300 times they performed the task.

There are similar formulation tasks for products other than sausage. For example, Task 06C01a2 directs inspection program personnel to check the formulas of products with requirements for minimum meat content. This task verifies compliance with the food standards that specify a minimum percentage of meat or poultry. FSIS has not used a laboratory analysis of the finished product to verify compliance with these types of food standards because food chemistry analysis measures protein and not meat or poultry content. Prior to HACCP implementation, task 06C01a2 was performed approximately 100,000 times annually. Inspection program personnel documented some problem or finding approximately once every 500 times they performed the task.

PBIS also included Task 07B01a2 that directed inspection program personnel to "check a sample of different labels to determine if labels are approved, correct, and used as intended." Until the 1995 generic label approval revisions to our regulations became effective, this task was performed almost 200,000 times per year. It was scheduled once every 2 weeks in all processing plants. Inspection program personnel were documenting some type of deficiency every 25 to 30 tasks. FSIS stopped scheduling this task in July 1996. It is now being performed at a substantially reduced rate on an unscheduled basis.

In 1994, the Headquarters staff obtained a sample of the Process Deficiency Record (PDR) on the above-referenced tasks to study the nature of labeling and formulation deficiencies. After reviewing those PDR's, the Agency made the following observations concerning tasks scheduled by PBIS:

First, there were incidences of noncompliance with our regulations that were documented only because inspection program personnel actually observed the violation occurring. The following illustrative example was extracted from three of the PDR's collected in 1994.

On day 1, while conducting Task 06A01a2, the inspection program personnel observed the addition of sodium phosphate

to a chopper preparing ingredients for a cooked sausage product that did not include phosphate on the ingredient statement. Sodium phosphate is a GRAS substance and did not present a food safety problem. Apparently, the plant agreed to hold the product, and plant management responded to the PDR that sodium phosphate would not be used in further production of the product. Two days later the same inspection program personnel observed the same problem, tagged the product, and issued a PDR indicating a repeat deficiency. Again, plant management responded, in writing, that sodium phosphate would not be used in the product. It appears the plant obtained approval of a new label showing phosphate in the ingredients statement and relabeled the product associated with both PDR's 10 days after the second incident. Approximately a month later the same inspection program personnel observed the same problem a third time. The third PDR did not indicate why the establishment was not using the new label.

It is highly unlikely that the above incident would have been detected through any product sampling program. Although compliance officers will collect samples if there is evidence suggesting the presence of unidentified phosphate or other undeclared ingredient, FSIS does not routinely analyze products for such substances.

Thus, as this incident illustrates, FSIS believes it will be important to continue to maintain in-plant inspection tasks as part of its overall OCP activities.

Second, the FSIS evaluation of the PDR's clearly suggested that the respective roles of industry and FSIS inspection program personnel were not well defined and understood. FSIS has discussed in many forums its conclusion that the line between the responsibilities of FSIS and those of the industry has often been blurred. The frequency of problems documented during label examination tasks evidences in our view that some establishments depend on FSIS to ensure accurate product labeling.

At the same time, while there has historically been a high deficiency rate for the labeling task (07B01a2), the findings do not necessarily indicate that labeling accuracy on finished consumer products is a major problem. The majority of labeling problems has not been associated with finished product labels. Rather, a large percentage has been related to FSIS enforcement of a requirement that all ingredients be identified at all times in storage coolers or in processing rooms. Examples of deficiencies from actual PDR's include: (1) a pallet of product on a loading dock had no identification on the outside of boxes, (2) a combo bin of trimmings in the processing room had no identification,

and (3) boxes of meat in cry-o-vac bags were stored in the holding cooler with no identification.

While the proper identification of ingredients is an important good manufacturing practice, a fair question can be raised as to whether component product needs to bear written identification if its identity is obvious to all. FSIS believes there is merit in the view that it should not be so intensely involved in an establishment's operating procedures that it monitors labeling as product is processed, and that it could more effectively use its resources to focus more on process control failures. Thus, we believe that inspection under the new ISP should focus on process control procedures and view instances of noncompliance as evidence of a lack of process control.

A third observation is that the PBIS tasks that focus on "correct formulation" can lead inspection program personnel to find deficiencies that are not tied to any regulatory noncompliance. Formulation can vary as long as such variation does not affect the order of predominance on the ingredient statement.

To illustrate, an inspection program personnel wrote a PDR while verifying the weights of the nonmeat ingredients for an entrée that is a nonstandardized product (pepper steak with rice and sauce). The PDR noted the following:

| <u>Ingredient</u> | <u>Approved Formula (lbs.)</u> | <u>Actual Weight (lbs.)</u> |
|-------------------|------------------------------------|---------------------------------|
| Chicken Fat | 205 | 123 |
| Diced Onions | 572 | 580 |
| Soy Sauce | 88 | 91 |

Since a product's formulation is permitted to vary as long as the variation does not affect the order of predominance on the ingredients statement, it would appear that a PDR was not warranted in this case because the variation from the formula (that accompanied the label approval) did not result in such a change. While the organoleptic characteristics of the product could be affected by this variation, this is of concern only to the establishment and not to FSIS. On the other hand, it is unclear whether the product of concern bore nutrition labeling. Observed variations in formulas could be used as a trigger to collect product samples to verify the accuracy of the nutrition labeling.

3. Laboratory Analyses

As noted earlier, collecting product samples for food chemistry analysis is an OCP activity used by FSIS to verify compliance with both food standards and labeling requirements. Samples are collected at federally inspected establishments, at import inspection facilities, and at various points in the food distribution chain, including warehouses and retail stores.

Laboratory analysis of food chemistry samples is an activity that has decreased substantially in recent years. In the 7-year period from 1979 through 1985, the minimum number of samples analyzed in any of these years by FSIS was over 93,000. In the late 1980's, the numbers dropped to the 60,000 to 70,000 range. The annual number has continued to decline. The totals for Fiscal Years 1995, 1996, and 1997 were 34,496, 23,229, and 18,099, respectively.

FSIS' information systems for laboratory results are not structured in a way to generate summary statistics concerning compliance with food standards or label requirements. Thus, we cannot easily conduct statistical analyses to establish the precise effect on our consumer protection objectives resulting from the decrease in food chemistry sampling. For example, FSIS cannot calculate the annual compliance rate for a particular regulatory requirement, such as fat in ground beef or fat in cooked sausage because the existing database that records laboratory results does not record the applicable regulatory requirement. Thus, a finding of 25 percent fat in ground beef may refer to the standard for a maximum 30 percent fat or a label claim of 20 percent fat. Our inability to summarize findings also limits our ability to target specific

products or regulatory requirements where noncompliance may be the highest.

FSIS has reduced food chemistry analysis as it has reallocated its resources to higher priority food safety concerns. FSIS has not, however, developed a process for reallocating remaining resources within food chemistry. As noted, overall food chemistry analysis declined 33 percent from 34,496 samples in FY 1995 to 23,229 samples in FY 1996. During the same time period, import samples dropped 85 percent from 3,123 in FY 1995 to 474 in FY 1996, while the number of samples collected by compliance officers increased slightly.

Samples are frequently analyzed for more than one attribute. For example, cooked sausage is normally analyzed for fat, total protein, and added water. Other food chemistry analyses include meat protein, total water, calcium in deboned product, and sodium to verify reduced sodium claims. The sampling of boneless poultry products is unique in that the standard sets a limit for bone content, while the laboratory analysis measures calcium content. The poultry regulations (9 CFR 381.117(d)) limit the bone content of boneless poultry to 1 percent, but this requirement is enforced by limiting the calcium content.

Not all food chemistry laboratory resources are used to directly measure compliance with food standards or label claims. For example, FSIS collects samples to verify Total Quality Control (TQC) or Partial Quality Control (PQC) programs operated by inspected establishments. FSIS also collects and analyzes samples for intra-laboratory quality assurance checks.

The remaining discussion on laboratory analysis for food chemistry is divided into the three general categories of surveillance samples scheduled by PBIS, centrally directed sampling for cured pork products, and samples collected by compliance officers. These three categories accounted for over 95 percent of the 23,229 samples analyzed by FSIS for FY 1996: 15,489 samples scheduled by PBIS, 6,162 centrally-directed samples for cured pork products, and 531 samples collected by compliance officers.

a. Sampling Scheduled by PBIS

In-plant sampling scheduled by PBIS accounts for the majority of food chemistry samples. These samples are collected to monitor compliance with regulatory requirements for fat content, added water, and other ingredients provided for in the existing food standards. Approximately two-thirds of these samples are for three products: cooked sausages, fresh pork sausages, and ground beef. The ISG

provided a sampling code for each product category that has a fat, water, or protein limit. The frequency of in-plant sampling is controlled by a frequency code set within the PBIS system. Thus, if an establishment produced ground beef, fresh pork sausage, and hotdogs, and the overall frequency was set for monthly, PBIS would randomly schedule three different sampling tasks within each month, one for each product category.

Changes in FSIS' approach to food chemistry analysis have thus far been limited to reducing the number of samples. The current approach still attempts to monitor the entire industry at a fixed level. Sampling is not targeted to establishments with a significant history of violations. There have also been no adjustments based on production patterns or marketplace changes.

The data for fat analysis of ground beef show that there have been significant changes in the production of ground beef. Existing regulations limit the fat content of ground beef and hamburger to 30 percent. Average fat content of ground beef has dropped every year from 1990 through 1997. In the 1990-1992 period, average fat content was approximately 21.5 percent. By 1997, the average fat content had dropped to 18.7 percent. In FY 1996, out of 1,546 samples, laboratory analysis showed only three samples

between 30 and 31 percent fat, four samples between 31 and 35 percent fat, and one sample over 35 percent.

Accordingly, given this information, FSIS believes it would be useful to consider adjusting the proportion of resources allocated to fat analysis of ground beef.

Data also show that some establishments have tight controls for fat in ground beef production. In FY 1996, we analyzed 18 ground beef samples from one such establishment, all between 22.6 and 25.9 percent. Sixteen of the samples were between 23.7 and 25.5, a range of less than 2 percent. Obviously, this establishment had control over fat content in ground beef. FSIS has concluded that these types of findings need to be incorporated into its resource allocation decisions. In performing its verification role, for example, FSIS could take fewer samples in situations where establishments have demonstrated greater control over their production process.

Additionally, FSIS believes it should break down the existing compartmentalization of its laboratory analysis program. For example, today ground beef samples collected for fat analysis are handled separately from ground beef samples collected for microbiological analysis. FSIS believes more multiple purpose analyses can be conducted,

thereby improving the efficiency and effectiveness of this program.

Finally, FSIS questions whether it makes sense to continue to allocate substantial resources to the analysis of the fat content of fresh pork sausage, a standardized product that is not permitted to contain more than 50 percent fat. It would be useful to reconsider this activity and its objectives and determine whether this activity still represents the best use of these resources or whether the resources would be more effectively used, for example, to ensure compliance with low fat claims or nutrition labeling requirements.

b. PFF Sampling

The existing food standards for cured pork products specify a minimum meat protein content expressed as a percent of the non-fat portion of the product. These food standards are referred to as "minimum meat Protein Fat Free (PFF) percentage requirements" or simply as "PFF requirements."

The Agency established the PFF requirements for cured pork products in 1984 because changes in production methods had made the existing compliance procedures ineffective. When FSIS published the new requirements, it also established, by regulation, a centrally directed sampling program to monitor compliance in each establishment. The

frequency of centrally-directed PFF sampling is based on several factors including production volume, number of product categories, and compliance history within product categories. Within an establishment, a product category could be under periodic or daily sampling or under sampling with product retention.

FSIS established the PFF requirements because it had concluded that excess added substances in cured pork products was a significant problem and that codifying a statistical compliance procedure was an appropriate solution. On the other hand, by codifying this program in the regulations, FSIS was, as a practical matter, taking responsibility for ensuring compliance, i.e., FSIS had instituted and was administering a government-run QC program. It is significant that the centrally directed program covers only producers of cured pork products that do not have quality control programs for added substances. FSIS concluded that it was not necessary to cover establishments with QC programs, since these plants had already assumed responsibility for meeting the standards.

While there are positive elements in the PFF sampling program, this activity too warrants further scrutiny. As with other OCP activities, FSIS believes the way in which resources are allocated to PFF sampling should be

reexamined. While the centrally directed PFF system does allocate resources based on compliance history, the allocation system only increases such resources. It does not reallocate sample collection and laboratory resources. Like certain other enforcement activities, e.g., the Progressive Enforcement Action initiative outlined in FSIS Directive 8830.1, the PFF system responds to compliance problems by increasing the expenditure of Agency resources. Experience has shown that increasing inspection or increasing the sampling rate does not necessarily increase the level of compliance.

The PFF sampling program also allows the Agency to summarize certain findings. For example, in FY 1996, the PFF database included 166 establishments producing "Ham, Water Added," the product that represents about 60 percent of the product monitored by the central system. Twenty of these 166 establishments had PFF violations leading to product retention actions in FY 1996. The available summary data are, however, of limited use in a programmatic sense because they do not include establishments with PQC programs. Summary data are also very difficult to extract because the database is organized to monitor specific products by establishment.

c. Samples Collected by Compliance Officers

In general, compliance officers collect product samples in response to either evidence suggesting regulatory violations or consumer, industry, institutional, or other complaints. Where in-plant sampling generally focuses on compliance with food standards, sampling by compliance officers usually focuses on potential acts of deliberate adulteration, such as adding cereal or soy protein to ground beef, species substitution, undeclared additives and preservatives, or water added to ground products.

B. Food Labeling - Net Weight

The PBIS system includes two tasks directly associated with net weight accuracy. One task directs inspection program personnel to check the accuracy of an establishment's scales and tare weight settings against available standardized weights. A second task directs inspection program personnel to check the scales and then perform a net weight check on a lot of product. Together, these tasks are conducted approximately 300,000 times per year. One or the other is scheduled every week in every processing establishment. Inspection program personnel document a problem in one out of every 150-product checks. The two net weight tasks account for the equivalent of 36 staff years of direct inspection time annually.

Although in some cases net weight violations may be evidence of deliberate attempts to short weigh, the relatively high frequency of problems documented during net weight examination tasks may also indicate that some establishments are relying on FSIS to monitor the accuracy of their scales and to ensure overall net weight accuracy. Accordingly, FSIS is reexamining its approach to net weight verification to ensure that inspected establishments take responsibility for complying with net weight requirements.

C. Food Labeling - Species Identification

FSIS conducts laboratory analyses of both raw and cooked products to determine whether products are accurately labeled as to species, i.e., the type of meat or poultry ingredient stated on product labels. Species testing covers both domestic and imported product. The Agency's laboratories analyze approximately 60 samples per month.

The Agency also uses the species identification field test (SIFT) and the Overnight Rapid Beef ID Test (ORBIT) to conduct in-plant screening. In-plant results indicating misbranding are sent to Agency laboratories for confirmation. Because of the nature of the laboratory test, species testing is part of the Agency's microbiological testing program and not its food chemistry program. This distinction is important for resource allocation decisions,

since, at this time, species testing does not compete for resources available to do fat, protein, and water analysis.

Species verification is an activity that falls in the gray area between food safety and OCP activities.

Obviously, product containing a species that is cheaper than that claimed in the labeling is economically adulterated.

False and incorrect labels may also, as stated previously, present a hazard for sensitive populations. FSIS intends to account for sensitive populations in designing new verification strategies.

D. Food Labeling - Nutrition Labeling

In 1996, FSIS contracted for a study involving nutritional analyses of a sample of 300 meat products and poultry products to compare the nutrient levels determined by laboratory analyses to the nutrient values presented on labels, thereby providing an overall assessment of the accuracy of the nutrition labeling on these products. This type of study may provide a useful model for FSIS as it considers restructuring its OCP activities. The study was designed to allow FSIS to draw a variety of conclusions concerning the level of compliance. The nutrition labeling project found that approximately 92 percent of all tested nutrients had values consistent with label claims. The labeling for total calories was accurate over 97 percent of

the time. The most out-of-compliance nutrient was vitamin A, for which only 73 percent of products had values consistent with label claims.

Such studies would allow FSIS to proceed in several different ways depending upon a careful evaluation of the results and current priorities. For example, the Agency could conduct follow-up testing on more products from establishments whose nutrition labels were out of compliance, or the Agency could initiate a targeted effort on vitamin A analyses if FSIS were to determine that it was a significant and priority concern.

E. Economic Adulteration of Raw Product

FSIS expends an estimated 25 to 50 staff years weighing poultry carcasses in 300 federally inspected poultry slaughter plants to ensure that poultry carcasses are not adulterated because of excessive retained water picked up during the immersion chilling process. The standard procedure calls for an inspection program personnel to collect and weigh a sample of 10 birds before and after chilling for each shift for each chiller system. Under this procedure, there can be several 10-bird samples in large establishments each day. FSIS conducts up to 100,000 of these tests annually. Many establishments, however, operate under reduced testing based on a history of compliance.

FSIS also monitors QC programs in meat slaughter plants that use spray-chilling systems. FSIS has required that meat slaughter establishments implement QC programs to monitor their chilling procedures to ensure that the weight of a group of chilled carcasses does not exceed the collective pre-final wash weight. With respect to water retention, FSIS needs to reexamine its approach to ensure that the Agency is verifying industry compliance and not administering a government-run QC program.

F. Raw Product Quality After Slaughter (Reinspection)

An AQL procedure is the term normally used to describe acceptance inspection procedures using attributes sampling. An AQL is a reinspection procedure conducted after carcass dressing operations and post-mortem inspection. An AQL is based on (1) selecting a sample of carcasses or carcass sides, (2) visually inspecting the sample to identify and classify defects according to standardized criteria, and (3) evaluating the defects to determine whether a lot is accepted or rejected, or whether additional sampling is required.

Boneless meat reinspection is an organoleptic inspection procedure, like a carcass AQL procedure, that applies "accept-reject" criteria to samples of boneless manufacturing meat. Criteria developed in the late 1960's

address manufacturing defects for boneless meat, including bruises, blood clots, bone fragments, and pieces of detached cartilage or ligaments. These criteria are based on the standard operating practices that existed when the criteria were established.

These defect criteria include defects related to food safety. For example, the extraneous material criteria for boneless meat address physical hazards such as glass or metal fragments. However, in establishments that have implemented HACCP, these hazards are addressed as part of the establishment's hazard analysis, conducted under the HACCP regulations in 9 CFR Part 417.

The boneless meat criteria and the carcass beef criteria are published in the Meat and Poultry Inspection (MPI) Manual. Poultry establishments under traditional inspection are subject to the poultry carcass AQL. The defect descriptions and criteria for the poultry AQL are published in MPI Directive 918.1. Most chicken slaughter operations and a substantial portion of turkey production are subject to the post-mortem inspection regulations for Streamlined Inspection System (SIS), the New Line Speed (NELS) Inspection System, or the New Turkey Inspection (NTI) System. Poultry slaughtered under these three systems is subject to the Finished Product Standards (FPS) contained in

9 CFR 381.76. The FPS is the only raw product quality criteria promulgated as regulations.

The beef carcass AQL is applied to carcasses that are shipped whole or shipped as parts of carcasses. FSIS has not applied the AQL to carcasses intended for in-plant boning because they are subject to boneless meat reinspection. Thus, fresh beef is subject to either the carcass AQL or boneless meat reinspection, but not to both tasks within the same establishment. Over the last two decades, the beef carcass AQL has been used less and less as more product is cut-up and boned before it is shipped. In the early 1990's, FSIS staff estimated that only 10 to 20 percent of carcasses were subject to the AQL.

The boneless meat reinspection task applies to certain boneless cuts/trimmings of meat. The task is conducted after the process of boning and before the product is used for further processing or shipped. Similar to the carcass AQL, the boneless meat reinspection task involves (1) collecting a sample of product using specific instructions, (2) examining the product to identify and classify defects, and (3) applying acceptance-rejection criteria to the lot that is sampled. Product that fails the criteria is retained, reworked, and then reinspected.

The inspection program uses two different procedures for boneless meat reinspection, a lot-based inspection procedure and an on-line procedure in establishments that have QC procedures for reinspection of boneless meat. The lot-based inspection task is conducted in approximately 2,000 establishments; the on-line task in approximately 800.

Lot-based boneless meat reinspection is a resource intensive procedure. The inspection task involves the physical examination of a sample of product. Before PBIS, in large establishments with multiple full-time processing inspection program personnel, the task was sometimes conducted from 15 to 20 times per week or more. When PBIS was implemented in 1989, the system was designed so that lot-based boneless meat reinspection would be scheduled approximately once per week. Data from the early 1990's show that approximately 80,000-90,000 lots were inspected, annually. The number of lots reinspected has decreased further since the early 1990's, indicating that the actual frequency is now less than once per week.

The on-line verification task is scheduled approximately once per week under PBIS. PBIS schedules two QC record reviews for each product examination.

FSIS does not have records on actual inspection task frequencies for on-line reinspection prior to the

implementation of PBIS. The direction to inspection program employee on this task was published in the MPI Manual. For on-line boneless meat reinspection, the Manual directed inspection program personnel to examine a 30-pound sample unit four times per day or two 30-pound sample units on each patrol visit.

There have been, and continue to be, differences of opinion regarding the appropriate level of inspection resources to be allocated to the boneless meat reinspection tasks. FSIS has significantly reduced the frequency of these tasks during the last decade, and yet, at the same time, there is little or no documentation supporting either past or present levels of verification.

FSIS is reexamining its consumer protection role for fresh meat quality and is considering both the need for standards and the design of appropriate verification strategies. Public input from all interested parties at this time would be particularly helpful in evaluating this OCP activity. Undoubtedly, many would view fresh meat quality as a factor controlled by marketplace incentives. The customers are usually other inspected establishments that have purchase specifications. From this perspective, one could view the boneless meat reinspection activity as a

quality control program for the industry funded by the government.

From a different perspective, however, it can be argued that meat trimmings are the primary ingredients of products like cooked sausage. These ingredients frequently go directly from a boning operation to a sausage kitchen within the same establishment and are never subject to marketplace incentives. It is reasonable to assume that consumers expect some oversight of this type of operation.

Today, there are five locations where FSIS conducts inspection of fresh meat for quality defects. First, carcasses are inspected on the slaughter line. Second AQL's are applied after chilling in the cooler. Third, at a "clean meat station," FSIS inspects product entering a cutting/boning room. The clean meat inspection is conducted after trimming and before boning. It involves an organoleptic inspection for product wholesomeness and does not utilize defect criteria, lot acceptance criteria, or uniform sample sizes. Fourth, fresh cuts such as steaks, roasts, chops, and slices are inspected during preparation or packaging. This procedure is similar to the clean meat procedure in that it does not involve defect criteria. The fifth and final task is the boneless meat reinspection as described above.

An Agency work group reviewed the fresh meat inspection criteria in the early 1990's. The group recommended that FSIS move in the direction of viewing fresh meat production as a single process, not a process of slaughter followed by a process of cutting and boning, each with its own inspection tasks with independent criteria. The group recommended the development of a single procedure combining the carcass AQL (or any successor), clean meat or pre-boning trim, and the boneless meat reinspection criteria.

Although the reinspection of poultry is somewhat different, PBIS includes a task for examination of poultry parts during cut-up and boning operations. While the task focuses on the temperature requirements for fresh poultry before and during further processing operations, it also covers a general inspection for wholesomeness.

The inspection of both fresh meat product and poultry for product quality has been a resource intensive and somewhat controversial component of the FSIS inspection program. As discussed above, public input from all interested parties would be helpful in evaluating the resource levels and priorities assigned to this OCP activity.

G. Carcass Sorting

The in-plant slaughter inspection system, i.e., the post-mortem inspection of meat and poultry, is a resource intensive activity that has served to meet not only vital food safety objectives, but other consumer protection purposes as well. FSIS uses inspection program personnel at fixed stations on each slaughter line to organoleptically identify and sort unacceptable carcasses and parts of carcasses from product that is acceptable for use as human food. While the sorting of carcasses clearly has an OCP component, this notice will not focus on those activities because they are being addressed as part of the Agency's initiative to examine new inspection models. This initiative is described in a Federal Register notice of June 10, 1997, "HACCP-Based Meat and Poultry Inspection Concepts," 62 FR 31553.

Some of the issues identified in the June 1997 notice are similar to issues raised here for the other components of the OCP program. For example, the June 1997 notice identified as a problem the fact that slaughter establishments have come to rely on FSIS personnel to sort acceptable from unacceptable product. The establishments have no incentive to remove carcasses and parts before presentation for inspection. Thus, the proper roles of industry and

inspection personnel are often obscured and FSIS' resources are not employed most effectively.