

characteristics of these products during refrigeration, transportation, and storage; and carcass cooling.

Interested persons may make presentations on these and related topics. Each presentation should be no longer than 15 minutes. FSIS will schedule about 15 to 20 presentations each day. Presentations will be scheduled on a first-come, first-served basis. Also, interested persons may display devices that are relevant to time and temperature control issues. Space for table-top displays is limited and will be allotted on a first-come, first-served basis. Contact Craig Zimmerman (see **FOR FURTHER INFORMATION CONTACT**) to make reservations for presentations or to display devices.

Done at Washington, DC, on: November 5, 1996.

Thomas J. Billy,
Administrator.

[FR Doc. 96-28743 Filed 11-5-96; 12:22 pm]

BILLING CODE 3410-DM-P

9 CFR Part 318

[Docket No. 96-027N]

Advanced Meat/Bone Separation Machinery and Meat Recovery Systems

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; request for public comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is soliciting data and information, from the public and industry, concerning the compliance requirements of its regulation entitled "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery Systems." FSIS also requests information and data on other approaches that might be utilized to assure that product derived from advanced meat/bone recovery systems is "meat." This action responds to concerns raised by consumer groups and industry members.

DATES: Comments must be received on or before January 7, 1997.

ADDRESSES: Send an original and two copies of written comments to: FSIS Docket Clerk, DOCKET #96-027N, Room 3806, 1400 Independence Avenue, SW., Washington, DC 20250-3700. Reference material cited in this notice and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 1:00 p.m. and from 2:00 p.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Charles R. Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700, (202) 254-2565.

SUPPLEMENTARY INFORMATION:

Background

On December 6, 1994, FSIS published a final rule titled "Meat Produced by Advanced Meat/Bone Separation and Meat Recovery Systems" that was effective on January 5, 1995. The final rule amended the definition of "meat" (9 CFR 301.2(rr)) to include as "meat" product resulting from advanced meat/bone recovery (AMR) systems that do not crush, grind, or pulverize bones to remove adhering edible skeletal tissue. The final rule provides the criteria under which these systems must operate for finished product from the systems to be called "meat."

The first criterion is a calcium content limit. This criterion was established to ensure that the meat derived from AMR systems is both consistent with consumer expectations of "meat" and comparable to meat that is used to formulate further processed meat food products. This criterion was included to ensure that bones are not crushed, ground, or pulverized during processing, i.e., that the processes are operating in control. The regulation requires that product resulting from the separating process not exceed a calcium content of 0.15 percent or 150 mg/100 gm of product with a tolerance of 0.03 percent or 30 mg.

The second criterion relates to the mechanism of the machinery involved and the appearance of the bones emerging from the AMR systems. AMR systems must not crush, grind, or pulverize bones, and the bones must emerge from the machinery comparable to those resulting from hand-deboning (i.e., essentially intact and in natural physical conformation so that they are recognizable as, for example, loin bones or rib bones when they emerge from the machinery).

If statistical evidence indicates that a production lot is not in compliance with the limit established for calcium content, the lot of product must be labeled "Mechanically Separated (Species) (i.e., Beef or Pork)" (MS(S)) (9 CFR 319.5) and meet all the requirements for MS(S).

MS(S) is a meat food product that is derived by crushing and pulverizing bones from livestock with attached edible tissue under high pressure and screening out the bone particles which

results in a paste-like material with a limited bone solids content. The machinery used to manufacture MS(S) causes bone and bone particles, including bone constituents such as bone marrow and certain minerals, to be incorporated into the finished product. A fundamental difference between the processed utilized for AMR systems and those utilized for making MS(S) is that the bones with attached meat that are the starting materials for deriving "meat" from AMR systems are essentially intact and recognizable when they exit the system crushed and pulverized during the process of making MS(S).

After the effective date of the final rule, consumer groups in meetings and correspondence alleged that the following occurs in the operation of certain AMR systems: (1) Bones are crushed, ground, or pulverized which violates the regulations, (2) bones are pre-sized to expose marrow which is being "harvested" as "meat," (3) bones emerge from certain systems in a compressed "cake," and, thus, are not essentially intact and recognizable, and (4) bone particles are screened out as a separate step after meat is separated from bone and before analysis to determine compliance with the calcium limit.

Responding to the consumer groups' contentions, FSIS surveyed a number of federally inspected meat establishments using AMR systems during October and November of 1995. Survey questions were distributed to inspection personnel at the establishments using the AMR systems. The following questions were asked:

- (1) What type of machine is being used; how does it work?
- (2) What are the starting materials; what bones with attached meat are used and are the bones split prior to processing, i.e., pre-sized, and to what size?
- (3)(a) What is the calcium content of the "meat" that is derived from the first step of removing lean tissue from the bone, i.e., the material that is pressed off the bone prior to desinewing?
- (3)(b) What is the calcium content of the "meat" that is derived at each of any subsequent deboning or desinewing steps?
- (4) Are the bones recognizable after the lean tissue ("meat") is recovered after the first step or any subsequent steps?
- (5) What other comments can you offer on the AMR systems?

Inspection personnel reported results from 52 establishments using meat/bone separators and recovery systems. Of the 52, four represented establishments that

used AMR systems to remove the bone from bone-in hams or pork shoulders which were never considered to be operations that were covered by the final rule. In the remaining 48 establishments, there were a variety of bones used as starting materials and some inspection personnel reported that pre-sizing occurred for some of these bones and that the bones were presized to between 4 and 14 inches. The type of bones and the degree to which bones were pre-sized was not reported to affect the calcium content of the meat produced or the assessment of bone appearance. The calcium content results reported from the 48 establishments represented results of analysis of samples of finished product, i.e., "meat" that exited the AMR systems.

Of the 48 establishments surveyed, inspection personnel in 13 establishments reported results that were not in compliance with either the calcium or bone criteria in the final rule. Of these 13 establishments, two establishments had product samples that were not in compliance with the final rule because their calcium content exceeded the limit established. Both of these establishments used an AMR system that had a one-step process. Calcium was found to be as high as 220 mg/100 gm of product. Inspection personnel reported, however, that bones exiting these systems were recognizable. The remaining 11 establishments had results that were not in compliance with the final rule because the bones exiting the system were not recognizable. In these 11 instances, calcium content did not exceed the established limit. One of the 11 establishments was using an AMR system that had a one-step process; the others used multi-step processing systems. In some of these 11 establishments, inspection personnel reported that bones emerged in a "cake" and, therefore, were not recognizable. Upon review of these findings and in subsequent discussions with inspection personnel, it was determined that, in many instances, the bones could be recognizable when the "cake" was disassembled. This point is addressed further in this document.

Representatives of certain establishments that operate AMR systems also met with Agency staff in regard to the advanced meat/bone separation regulations. These representatives stated that (1) the regulations do not require that samples taken after "intermediate" separation stages conform to the calcium limit, and that there is compliance with the established calcium content limitation of the regulations if the finished product that will be called "meat" meets the

regulation's calcium criterion, (2) FSIS was aware that multi-step systems were in use before the regulations were published and intended that their use be continued, (3) the regulations do not prohibit the bones from emerging from the machinery in a "bone cake" provided they are intact and recognizable when disassembled, and (4) continued use of AMR systems should be encouraged since they produce a safe product without the cumulative trauma disorders (e.g., carpal tunnel syndrome) experienced by establishment personnel whose work entails hand deboning.

The Agency has reviewed the issues raised by the consumer groups and the industry. The regulations were designed to allow manufacturers the flexibility to develop and use any technology that would remove meat from bones of livestock without crushing, grinding, or pulverizing the bone, and that would result in product that satisfied the established calcium content limit. Thus, an AMR system, regardless of whether it involves a one-step or multi-step process, can be used to produce product identified as "meat," as long as the operations of these systems, and the product exiting the systems, meet the regulation's criteria.

The rule's flexibility is consistent with prior FSIS policies reflected in an "Inspection Procedure" and then in a Partial Quality Control (PQC) program (#812) requirement. As discussed below, the final rule involves two criterion that must be met, for the product that emerges from the AMR systems to be classified "meat."

First, as discussed earlier, the regulation requires that product exiting AMR systems meet a calcium limit of 150 mg/100 gm of product within a tolerance of 0.03 percent (30 mg). The compliance procedure provided in the regulation focuses on the finished product derived from the systems, and requires sampling for calcium of "meat," from production lots. In this regard, noncompliance occurs when calcium analyses of the samples of meat from finished lots exceed the established calcium limit. When calcium results exceed the limit, the product must be called MS(S), e.g., mechanically separated beef or pork, and comply with the regulations on MS(S).

Second, the bones emerging from AMR systems must emerge comparable to those from hand deboning. Therefore, if pre-sizing of bones results in bones that are not recognizable, the product exiting the AMR systems could not be identified as "meat." The rule clearly intends that establishments ensure that

their systems are operating in control and in accordance with the regulations. Thus, establishments need to carry out procedures to ensure that bones exiting the AMR systems are comparable to those resulting from hand-deboning (i.e., essentially intact and in natural physical conformation such that they are recognizable, such as loin bones and rib bones, when they emerge from the machinery. Establishments must also carry out the calcium content analysis procedures required, and, in turn, comply with the regulation's requirement in cases where compliance with the calcium content limit is not demonstrated. Although establishments are responsible for assuring that they comply with the regulations, FSIS inspectors will also verify establishment operations, which may include periodic examination of bones exiting AMR systems, to ensure that such systems operate in accordance with the regulations.

FSIS believes that the provisions in the AMR regulations must be consistently enforced. FSIS enforcement serves to ensure establishment compliance with the two criteria that must be met in order for product exiting from AMR systems to come within the definition of "meat." FSIS has issued instructions to field personnel so that they will have a consistent understanding of their role and receive uniform guidance in ensuring that establishments comply with the regulations.

FSIS is reviewing all establishments which operate AMR systems at least once per week to ascertain if the establishments are operating in compliance with the regulations. Reviews are scheduled through the Agency's Performance Based Inspection System and are currently being conducted. FSIS Reviews examine available establishment records required to be maintained regarding the calcium content limit of product classified as "meat" and actions taken by the establishment if the calcium limit is exceeded. FSIS is also examining representative samples of bones before they enter and after they exit the AMR system to determine if the bones emerge from the AMR system essentially intact and in natural physical conformation.

Request for Data and Information

FSIS welcomes views and information on approaches, other than those set forth in the current rule that might be utilized to ensure that product derived from AMR systems is "meat." FSIS also invites comments and data pertaining to several issues raised by interested parties.

The compliance requirement for calcium content limitation in the regulations applies only to the finished product (i.e., meat) exiting the AMR systems. The regulation does not require the calcium content limitation of the rule to be met regarding material from an interim phase of the continuous operation of the AMR systems (i.e., "intermediate" material). To implement a requirement that calcium analysis be made on "intermediate" material obtained after the first separation step of an AMR system which comes before subsequent desinewing or separation steps (as requested by consumer groups), and that for product to be identified as "meat" such analysis must indicate that product from the intermediate step met the calcium content limitation, FSIS would need to amend the regulations. Any such modification must be based on substantive data which supports the need for such a requirement. FSIS invites data and comments pertaining to this issue.

The Agency believes that establishments operating AMR systems recognize the need to have controls for their AMR systems which ensure that the condition of the bones exiting the systems conform to the regulations. However, there are no recordkeeping requirements imposed by the regulations. Records of the condition of bones before and after they exit the AMR system's machinery could facilitate FSIS' determination of whether bones exiting the systems are intact and recognizable. FSIS invites comments regarding the need to modify the compliance procedures to include recordkeeping requirements to show that bones that emerge from the systems are being monitored by the establishment.

FSIS is also interested in receiving data to assess certain issues raised by interested parties. FSIS is interested in data and comments on the following questions: (1) What practices are being conducted in regard to presizing and do these have any effect on bone recognition? Should presizing criteria be established that would establish the minimum dimensions a bone must be to be allowed to be used in the AMR systems? (2) If the calcium content of the material being separated in AMR systems is higher at an interim stage of the process than that established for the finished product (i.e., 150 mg/100 gm of product, within a tolerance of 30 mg), does this mean bones have been crushed, ground, or pulverized and is there data to support such a conclusion? (3) If the "meat" derived from the AMR system conforms to the definition of

meat, i.e., it does not exceed the calcium limit and the bones are essentially intact and recognizable, are there other helpful compliance measures that should be examined, and, if so, why? (4) Should the current criteria requiring that bones emerge essentially intact and in natural physical conformation be further qualified to indicate that only minor abrasions of bone edges or removal of minute amounts of bone would be permitted in order to meet this criteria? What standards should be established as indicators that these standards have been met? The answers to these questions require data that are representative of the various AMR systems used. These data are currently unavailable to the Agency. FSIS is seeking comments from all interested parties on the issues raised in this notice and specifically encourages the submission of views and data by equipment manufacturers.

FSIS has also received letters from various consumer groups which assert that bones are being pre-sized, then crushed, ground, and pulverized in AMR systems to "harvest" marrow. The assertions focus on marrow allegedly "harvested" from beef neck bones due to the operation of two pieces of press-type meat/bone separation equipment. The document provided to FSIS to support these assertions was a University of Nebraska doctoral dissertation on "mechanically recovered neck bone lean (MRNL)." This dissertation, as well as peer-reviewed journal articles based on the research reported in the dissertation, have been reviewed by FSIS. The research focused on examining the characteristics of MRNL derived from beef neck bones processed using two types of meat/bone separators. The objective of the research was to investigate the functional characteristics of the material derived from the neck bones in order to provide information about how the material can be used to formulate other products. The objective of the research was not, however, to test how AMR systems operate or to make determinations in regard to what the composition is of the finished product derived from AMR systems. Therefore, FSIS does not believe that the research can be used to support a conclusion that bones are being presized then crushed, ground, and pulverized in AMR systems to "harvest" marrow. FSIS did consider the issues of bone residue and marrow during development of the AMR regulations. In both the proposal and final rule, FSIS stated that the contribution of bone content to meat resulting from AMR systems is minimal.

It would be no greater than that which may occur if bone surfaces are abraded, pressed, or scraped to expose bone content as part of hand-deboning operations. Further, FSIS concluded the potential contribution of bone marrow, a portion of a bone's content, to meat from AMR systems poses no health or safety hazards nor would it be at a level which would make its inclusion an adulteration or misbranding issue.

The internal part of livestock bones is composed of the same constituents as "meat," and consists of adipose (fat) tissue, connective tissue, and marrow. Bone marrow is a fraction of the internal bone content and also is part of the animal's vascular system. When an animal is slaughtered, most of the red (blood) marrow is lost. The remaining red marrow is mostly red blood cells. Red (blood) marrow is found in higher amounts in certain bones, e.g. the long bones of animals (i.e., the femur, shank, and patella, etc.). Long bones remain with primal and sub-primal cuts and eventually are cut into retail portions of "meat" or are used to make soups, stocks, and broth. Bones used in the AMR systems are typically the flat bones (e.g., vertebrae, sternum, ribs, and pelvis) with adhering tissue and contain relatively little marrow.

There are no standardized methods to determine marrow content because it is composed of the same constituents as "meat" and, therefore, it is difficult to analytically distinguish it.

There are some experimental approaches that attempt to quantify marrow based on a constituent of marrow, e.g., cholesterol, amino acid, fatty acid, nucleic acid, mineral, and vitamin content, or pH. However, there are many factors that relate to natural variations in marrow and meat composition that disqualify these methods from being relied upon as standardized methods. Therefore, the suggestion by various consumer groups that cholesterol and iron are unique markers for marrow is generally unsupported by the scientific literature. Similar to that expected in hand-deboning operations, it is conceivable that when a pre-sized bone is pressed, compressed, or scraped in an AMR system, it may express some bone content through cracks or openings at the ends of the bone that may be incorporated in product. This material would consist of the fluid portion of the bone content (e.g., red (blood) marrow and some fat). However, it is not necessarily marrow that is expressed into the meat from AMR systems, it could just as likely be blood and fat which are part of "meat" as defined in the regulations. This would account for

the minor color differences of neck bone meat from AMR systems and hand-deboned neck meat. However, because the connective tissue structure of the internal portion of bone maintains the integrity of most of the bone's semi-solid and solid content, and this remains intact in AMR systems, most of the bone's content is not expressed when AMR systems are utilized. In contrast to this, a more physically rigorous process, e.g., the mechanical separation process yielding MS(S) that crushes, grinds, and pulverizes bones would, of course, destroy the internal bone structure and evenly distribute all the contents of the bone in an amorphous tissue mass.

Although FSIS does not currently know of any standardized methods to determine the presence of bone marrow in meat products, FSIS would like data that can help establish what constituents are unique to marrow that can be relied upon to indicate the presence of bone marrow in meat products. If such a standardized method could be established, FSIS would like comments on whether a compliance criterion regarding marrow should be established in regard to product derived from AMR systems. In this regard FSIS would like comments on the following questions. (1) Should an acceptable level of marrow be established for meat and product derived from AMR systems? If such a level was established, should the presizing operations of AMR systems be examined to determine if they contribute to the marrow content of product derived from AMR systems? (2) If the product derived from the AMR systems is determined to have an amount of marrow higher than that found in hand deboned meat, should such products be designated as MS(S) rather than meat? (3) Is it possible to establish criteria on the amount of marrow in product from AMR systems based on the degree to which bones emerging from the AMR systems are hollow?

FSIS Studies

In addition to requesting comments and data from the public, FSIS itself will also collect information on how AMR systems are currently performing.

The Agency is interested in collecting information regarding the recovery of tissue from bones by use of AMR systems, especially the recovery of tissue from split neck bones of beef. Compliance procedures for the AMR systems were designed to assure that bone, as measured by calcium content, was not intentionally incorporated into product. FSIS was aware that desinewing equipment was being used

in conjunction with the AMR systems to remove hard particle tissues (e.g., bone fragments, ligaments, tendons, cartilage) inherent to boning operations. FSIS believed that AMR systems which were not being operated in compliance (i.e., which crushed, ground or pulverized bones) would be identified through the calcium check of the finished product. This conclusion was based on the view that desinewing equipment would not remove a significant amount of the powdered bone which would result from crushing, grinding, or pulverizing, and consequently the finished product would exceed the calcium limit. In an effort to assure that the desinewing equipment is not being used to remove excess powdered bone resulting from bone breakage, FSIS is taking steps to better identify what the desinewing equipment is removing. A sampling plan is being devised which will statistically establish the expected calcium content of a product derived from a properly operating AMR system, prior to and after desinewing.

In another study, FSIS will be identifying the expected range of calcium, cholesterol and iron contents, the pH level, and the texture and appearance of various products which qualify as "meat." The Agency intends to involve the Agricultural Research Service (ARS) in this activity. Representatives from ARS were involved in the initial steps leading up to the development of the regulation. This study will assist FSIS in learning more about the issues concerning marrow in AMR products that have been raised.

Done at Washington, DC, on November 4, 1996.

Thomas J. Billy,
Administrator.

[FR Doc. 96-28768 Filed 11-5-96; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[Docket No. EE-RM-94-230A]

Energy Conservation Program for Consumer Products: Test Procedure for Clothes Washers and Reporting Requirements for Clothes Washers, Clothes Dryers, and Dishwashers

AGENCY: Office of Energy Efficiency and Renewable Energy, DOE.

ACTION: Proposed rule; limited reopening of the comment period.

SUMMARY: Appendix J to subpart B of 10 CFR part 430 sets forth the test procedures required for testing whether clothes washers comply with the existing energy conservation standards. The Department of Energy (DOE or Department) has proposed to amend these test procedures. The purpose of this notice is to solicit comments on possible additional amendments which would require certain specific procedures for testing clothes washers with adaptive (machine controlled) water fill control capability, and clothes washers with non-traditional temperature selections.

DATES: Written comments in response to this notice must be received by November 25, 1996.

ADDRESSES: Written comments, 10 copies, are to be submitted to: U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, EE-43, Room 1J-018, "Test Procedure for Clothes Washers and Reporting Requirements for Clothes Washers, Clothes Dryers, and Dishwashers," Docket No. EE-RM-94-230A, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585, (202)-586-7574.

Copies of the transcript of the public hearing and the public comments received on the proposed rule, may be read or photocopied at the Department of Energy Freedom of Information Reading Room, U.S. Department of Energy, Forrestal Building, Room 1E-190, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586-6020 between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

P. Marc LaFrance, U.S. Department of Energy, Energy Efficiency and Renewable Energy, Mail Station EE-43, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585-0121, (202) 586-8423

Edward Levy, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC-72, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-9507

SUPPLEMENTARY INFORMATION:

I. Introduction

II. Discussion

A. Adaptive Water Fill Control

Manual and Adaptive Water Fill Control
Multiple Adaptive Water Fill Control Settings

B. Temperature Selections

Multiple Warm Wash Temperature
Combination Selections
Multiple Temperature Settings within a
Temperature Combination Selection