DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318, 319, and 381

[Docket No. 93–008F]

RIN 0583–AB68

Poultry Products Produced by Mechanical Separation and Products In Which Such Poultry Products Are Used

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal poultry products inspection regulations to prescribe: a definition and standard of identity and composition for the poultry product that results from the mechanical separation and removal of most of the bone from skeletal muscle and other tissues of poultry carcasses and parts of carcasses (''Mechanically Separated (Kind of Poultry)''—hereafter referred to generically as ''Mechanically Separated Poultry'' (''MSP'')), including requirements for bone solids content (measured as calcium content) and bone particle size; certain limitations for the use of MSP; and labeling requirements for MSP, and for poultry products and meat food products containing MSP as an ingredient. This action establishes the requirement that products containing MSP as an ingredient disclose that fact by identifying it in the ingredients declaration as, in the case of MSP derived from chicken carcasses, ''mechanically separated chicken,'' rather than ''chicken.'' This action will help ensure that meat and poultry products distributed to consumers are not labeled in a false or misleading manner and are not misbranded.

EFFECTIVE DATE: November 4, 1996.

FOR FURTHER INFORMATION CONTACT: John W. McCutcheon, Deputy Administrator, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, Area Code (202) 720–2709.

SUPPLEMENTARY INFORMATION:

Purpose of the Final Rule

This final rule amends the regulatory requirements for the poultry product with a paste-like form and batter-like consistency that results from the mechanical separation and removal of most of the bone from attached skeletal muscle and other edible tissues of poultry carcasses and parts of carcasses, and for the finished poultry products and meat food products in which this product is used as an ingredient. FSIS first conducted a rulemaking regarding this product in 1969. Over the years, the amount of such product being manufactured, and the number and range of poultry products and meat food products in which it is used as an ingredient, has increased significantly.

FSIS has gained a great deal of knowledge from its rulemakings regarding the livestock product resulting from a similar mechanical separation and removal process which is called ''mechanically separated beef'' or ''mechanically separated pork'' (or any other species derived from livestock, such as beef, and lamb), which will be referred to generically in this document as mechanically separated meat (MSM). MSM is a livestock product with a paste-like form and batter-like consistency that results from the mechanical separation and removal of most of the bone from attached skeletal muscle of livestock carcasses and parts of carcasses that meets the provisions of 9 CFR 319.5. MSM is subject to regulatory requirements which include a standard of identity and composition that defines this product, limits for bone solids content and bone particle size, and a name that differentiates it from meat. It is also required to be separately identified in the ingredients statement of products in which it is used, and is subject to certain restrictions in its use.

More recently, in a lawsuit, *Bob Evans Farms, Inc. et al., v. Mike Espy, Secretary of Agriculture (D.D.C. Civil Action No. 93–0104)*, several red meat sausage manufacturers alleged that, without a regulatory definition and standard for poultry products produced by mechanical separation, a disparate situation exists between labeling MSP, and MSM for which a regulatory definition and standard exist. The red meat sausage manufacturers have alleged that the disparate labeling situation poses an unfair advantage for the manufacturers of mechanically separated poultry products.

In view of these developments, and taking into account the information and experience acquired since 1969 and current regulatory policies, the Agency has reviewed and reevaluated the existing regulations for MSP, particularly in regard to labeling issues about this product. As a result of its review and reevaluation, the Agency has concluded that regulatory action to more clearly identify MSP on product labels, is necessary to prevent the preparation and distribution in commerce of poultry products and meat food products which are misbranded or not properly marked, labeled, or packaged. See sections 4(h) and 8 of the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) and sections 1(n) and 7 of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*); 21 U.S.C. 453(h), 457 and 601(n), 607. The primary reasons for this action are as follows:

(1) The method of deriving poultry products by the mechanical separation process results in a product whose physical form and texture differ materially from those of other boneless poultry products produced by hand deboning techniques, i.e., hand-held knives.

The process of manufacturing MSP begins with starting materials that include backs, and whole and half carcasses and parts of carcasses from which most of the muscle and other tissues have been removed by hand, leaving bits and pieces of tissue adhering to skeletal frames and carcass ''shells.'' These starting materials may be raw or cooked, may contain varying amounts of muscle and/or skin (with or without attached fat), and may contain kidneys, except when product is made from mature chickens or turkeys. (Kidneys of mature chickens or turkeys may not be used as human food according to 9 CFR 381.65(d)). The nature of these starting materials is such that the muscle and other tissue that remains on the bones cannot be efficiently or effectively removed using hand-deboning techniques. This is because (1) the bony structure of the materials limits the accessibility of knives and obstructs precise hand removal of edible tissue, (2) hand-removal of the tissues is too time consuming to make it practical, and (3) the physical movements necessary to remove the bits and pieces of tissues adhering to bones have been associated with cumulative trauma disorders (also referred to as repetitive motion disorders), e.g., Carpal Tunnel Syndrome. Mechanical separation of the bits and pieces of muscle and other tissues from the bones to which they are adhering is, however, easily accomplished using mechanical deboning machines.

Typically, the starting materials have undergone an initial bone breaking process to enable the machines to operate efficiently. The starting materials are fed into a mechanical deboning (i.e., separation) machine which operates on the differing resistance of bone and tissue to passage through small holes (i.e., apertures), whether it employs sieves, screens, or other devices. The starting materials are pushed under high pressure through the part of the equipment with apertures. Most of the bone is separated and

removed. However, the apertures allow a small amount of powdered bone to pass through with the edible tissues, which, under the high pressure applied by the machine, become a homogeneous soft tissue mass. The minute amount of powdered bone (particles much smaller than the size of pepper and limited to no more than one percent) is also dispersed throughout the soft tissue mass. The remaining bony residue that has been separated from the paste-like muscle and other tissues exits from a separate place on the equipment. Thus, such machines mechanically separate and remove most of the bone from the starting materials, resulting in a product with a paste-like form which is comparable in consistency to a cake batter. The process of manufacturing mechanically separated poultry results in a product whose form and texture differ materially from those of other boneless poultry products produced by traditional hand-deboning. Despite these differences, current FSIS regulations do not distinguish between poultry products produced by mechanical separation and poultry products produced by traditional deboning techniques, i.e., hand-deboning, in terms of product identity and composition or use. Both are declared on product labels as ''chicken,'' ''turkey,'' or the names of other kinds of poultry.

(2) Mechanically separated poultry is produced by essentially the same technology and has characteristics (i.e., physical form and textural consistency) similar to those of the livestock product, MSM, which is required to be declared on labels as mechanically separated beef (or pork or other species of livestock).

(3) The mechanical process from which mechanically separated poultry is derived makes its form and consistency materially different from that of poultry derived by traditional hand-deboning methods, yet it is not currently identified in the ingredients statement of a product in which it is used by a name that distinguishes it from traditionally deboned poultry. Mechanically separated poultry should be declared in the ingredients statements of the products in which it is used by the distinctive term ''mechanically separated (kind of poultry),'' e.g., ''mechanically separated turkey,'' ''mechanically separated chicken.''

The product resulting from mechanical separation has certain textural attributes that are different than hand-deboned poultry, even if the hand-deboned poultry is further processed through a grinder to result in ground poultry. The product that directly results from the mechanical process is paste-like in form and similar to a cake batter in consistency, and is not the same as chicken or turkey removed from carcasses or parts of carcasses by hand. Chicken or turkey that results from hand-deboning is easily recognized as muscle, skin, and other edible tissues and parts because it retains its natural physical form and consistency; it has not been subjected to the rigors of crushing bones and separating bone from muscle and other tissue under high pressure in separation machinery. The rigors of the mechanical separation process alter the structure of the muscle fibers, skin, fat, and other tissues that adhere to the skeletal frames, shells, and other starting materials so that they become blended and amorphous, and are no longer recognizable as ''chicken'' and ''turkey.'' These machines are not available to consumers and, therefore, consumers are not likely to have the expectation of the resulting batter-like material as ''chicken'' or ''turkey.'' Thus, a separate identity is necessary for the product that results.

The term ''mechanically separated'' is recognized internationally by the Codex Alimentarius Commission [1] of the United Nations and by individual countries that trade with the United States, has been upheld in Court decisions as being appropriate to distinguish the livestock product derived by mechanical separation machinery [2], and appropriately distinguishes the product from hand-deboned poultry as one that is derived by a strictly mechanical means. As such, similar terminology should be applied to poultry products resulting from the process of mechanical separation and recovery of crushed bone from muscle and other edible tissues that results in a product with a paste-like form and cake batter-like consistency.

Therefore, FSIS is amending the poultry products inspection regulations (9 CFR Part 381) to revise and supplement the requirements for the manufacture, characteristics, and labeling of poultry products produced by mechanical separation and the labeling of products in which they are used as ingredients that result in a product with a paste-like form and cake batter-like consistency. Under this final rule, mechanically separated product derived from chicken or turkey would be labeled as ''mechanically separated chicken,'' or ''mechanically separated turkey,'' as the case may be, and would be separately identified by this name in the ingredients statement of products in which it is used.

The Purpose of An Extended Effective Date

Various commenters suggested that industry should be given a sufficient amount of time to use most of their already printed labels, before the final rule's new labeling requirements must be carried out. FSIS agrees that such a time period should be granted in regard to all of the new requirements of the final rule. Therefore, an effective date of one year from the date of publication has been provided for in this final rule. This time period is intended to allow ample time for an orderly transition to the new requirements, including the labeling requirements, and to assure that manufacturers of poultry products produced by mechanical separation, and of poultry and meat food products in which the product is used as an ingredient, have ample time to exhaust current label stock. In this regard, manufacturers will not be required to dispose of label inventories that were printed or ordered for printing prior to publication of the rule if they have made a good faith effort to exhaust current stocks before the effective date. Requests for use of current labels beyond the effective date will be considered on a case-by-case basis.

Background

I. Introduction

The technology to mechanically separate and remove most of the bone from attached skeletal muscle and other tissue of poultry carcasses and parts of carcasses began in the late 1950's or early 1960's. The technology is grounded in the desire of poultry manufacturers to salvage edible, wholesome muscle and other tissue from carcasses and parts of carcasses (such as skeletal frames and carcass shells) that cannot be efficiently or effectively removed by hand in order to provide a source of low-cost protein that is safe and essentially nutritionally the same as the muscle and other tissue removed from poultry carcasses and parts of carcasses by hand deboning methods. In terms of functionality, mechanically separated poultry has the same functions as hand-deboned chicken or turkey with the added

[1] Food and Agriculture Organization of the United Nations, World Health Organization, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Volume 10, Code of Practice for Mechanically Separated Meat and Poultry, pp. 71–72 (1994) is available for review in the FSIS Docket Clerk's office.

[2] A copy of the Courts' decisions in *Community Nutrition Institute (CNI) et al. v. Block*, No. 82–2009 (D.D.C. Dec. 1, 1982), aff'd 749 F.2nd 50 (D.C. Cir 1984) is available at the FSIS Docket Clerk's office for review.

benefit of being able to easily form emulsions and bind to other proteins readily. This is because the muscle and other edible tissues no longer possess their original tissue structure and the cake-batter consistency eases blending with other ingredients.

The Agency's initial reaction was to consider the resulting product adulterated because of the amount of powdered bone present and the physical size of the bone particles. By the mid-1960's, the industry had modified and improved the equipment used to produce poultry product by mechanical separation such that the product contained 1 percent or less bone solids with an extremely small bone particle size. This prompted the Agency to reevaluate its position. Widespread commercial production of products containing mechanically separated poultry began in the early 1970's. By 1975, poultry product produced by mechanical separation was being used as an ingredient in poultry and meat food products such as franks, bologna, salami, and poultry rolls.

Today, the technology for producing poultry products by mechanical deboning is accepted as a valuable and practical means for salvaging edible tissue from poultry parts and carcasses from which most of the muscle and other tissues have been removed by hand. In the current market, poultry products made with mechanically deboned poultry include cooked poultry sausages (such as chicken frankfurters, turkey salami, and turkey bologna), poultry patties and nuggets (such as chicken patties and nuggets), formed and whole poultry roasts (e.g., oven-cooked turkey breast), and poultry baby foods. The level at which it is used has depended in part on technological capabilities. For example, the level of use has reached 100 percent of the poultry product portion of a number of cooked poultry sausage products (such as chicken franks) and greater than 15 percent of the poultry product portion of whole muscle products, e.g., cooked turkey breast, where it serves the purpose of binding whole muscle pieces together to make the product. Poultry product produced by mechanical means is also used at up to 49 percent of the formulations of certain meat food products, e.g., beef and turkey chili, provided that it is identified in the product name as ''turkey'' or ''chicken,'' and used in meat food products including cooked sausages, such as frankfurters and bologna, at a level of up to 15 percent of the total ingredients, excluding water (9 CFR 319.180) without being identified in the product name.

Over the years, the poultry and meat food industries have also referred to poultry products produced by mechanical means as ''comminuted (i.e., ground) poultry.'' Terminology such as ''finely comminuted,'' ''finely ground,'' ''mechanically deboned,'' and ''mechanically separated'' have also been used to describe the product according to 9 CFR 381.117(d). The terms ''finely ground,'' ''ground,'' ''finely comminuted,'' and ''comminuted'' have been applied to poultry produced by mechanical deboning as well as to poultry products produced using hand-deboning methods as a means of being in accord with 9 CFR 381.117(d).

Poultry products produced by mechanical means are currently subject to 9 CFR 381.117(d) which relates generically to boneless poultry products. This regulation requires boneless poultry products to be labeled in a manner that accurately describes their actual form and composition. The product name must indicate the form of the product, e.g., emulsified or finely chopped, and the kind name of the poultry from which it is derived, e.g., chicken, turkey, etc.. If the product does not consist of natural proportions of skin and fat, as they occur in the whole poultry carcass, the product name must also include terminology that describes the actual composition. If the product is cooked, it must be so labeled. Section 381.117(d) also limits the bone solids content of boneless poultry products to 1 percent.

Existing regulations do not distinguish between boneless poultry products produced by mechanical separation and poultry products produced by traditional methods, e.g., hand-deboning. As a matter of practice, poultry product produced by mechanical separation is currently declared in the ingredients statement of a product in which it is used, along with any other boneless poultry product used, as ''chicken'' or ''turkey'' where skin and fat are included but not in excess of their natural proportions, or as ''chicken meat'' or ''turkey meat'' when skin with attached fat is not included.

II. Report on Health and Safety of Mechanically Deboned Poultry

In 1976, FSIS initiated an analytical program to obtain data on a number of nutrients and substances of potential health concern in poultry products produced by mechanical separation. Data were also gathered from scientific literature, industry, other government agencies, and university scientists. Details of the analytical program and a resulting evaluation were published in a June 1979 report entitled ''Health and Safety Aspects of the Use of Mechanically Deboned Poultry'' (hereafter referred to as the 1979 Report). An errata supplement correcting certain items in the report was prepared and published on August 14, 1979 (44 FR 47576). (The 1979 Report and the errata supplement are available for public inspection in the FSIS Docket Clerk's office.) On June 29, 1979, the Agency announced the availability of this report and encouraged interested members of the public to comment on its content.

The 1979 Report evaluated the effects on health and safety of use of mechanically separated poultry and, in particular, examined the heavy metal, trace element, bone particle, chlorinated hydrocarbon, cholesterol, fat, essential amino acid, total protein, and purine contents of MSP, as well its microbiology. The 1979 Report recommended that (1) potential health risks associated with cadmium in kidneys from mature chickens would be avoided by not allowing kidneys from mature chickens in MSP, (2) potential risks to children associated with fluoride in MSP from fowl could be avoided by not allowing MSP from fowl in baby foods, (3) MSP should be labeled to show the presence of cholesterol and calcium for the benefit of people who needed to restrict their intake of these substances, and (4) mandatory handling and storage of starting materials used for making MSP should be considered.

In the same June 29, 1979, announcement on the availability of the 1979 Report, FSIS also notified the public that it was particularly interested in receiving comments regarding the proper labeling of products containing poultry product produced by mechanical separation and what means, if any, should be taken to implement the labeling recommendations with regard to calcium and cholesterol in the report (44 FR 37965).

FSIS received 221 comments, most of which were general reactions to the labeling issues raised in the notice, and health, safety, or economic concerns. The majority of the commenters expressed a general opinion on the adequacy of regulations concerning mechanically separated poultry products and were supportive of the rules at that time. Some commenters stated that the regulations have effectively controlled the use of mechanically separated poultry products over many years with a wide base of consumer acceptance, that such product is not significantly different from product produced by hand-

deboning, that these regulations provide truthful labeling, and/or that the report and scientific literature support the adequacy of current regulations. Other commenters indicated that mechanically separated poultry should be regulated the same as mechanically separated meat (then named mechanically processed (species) product).

III. GAO Report on Mechanically Separated Products

In 1983, the General Accounting Office (GAO) issued a report recommending that the Secretary of Agriculture direct the Administrator of FSIS to establish specific standards on poultry products produced by mechanical separation, and labeling requirements on products made with such poultry products, as had been done for MSM and products made with MSM.

IV. Improvements in Machinery for Poultry Products Produced by Mechanical Separation

The Agency has monitored the advances in the technology for mechanically separating poultry over the last decade. There have been improvements in the efficiency of the mechanical separation and removal of most of the bone from attached skeletal muscle and tissue of poultry carcasses and parts of poultry carcasses. Today, industry figures estimate that roughly 1 billion pounds of raw poultry materials are used to manufacture 700 million pounds of mechanically separated poultry, which is used, in turn, to formulate approximately 400 million pounds of poultry sausages (including franks, bologna, and salami), and 300 million pounds of poultry nuggets and poultry patties.[3] There have been major advances in mechanical separation machinery in terms of the effectiveness of removing the bone which is incorporated by the process of separation into the skeletal muscle and other tissues of poultry carcasses and parts of carcasses. This has been accomplished through enhancements and modifications of the bone-removal devices that are part of the mechanical deboning machines. There have been continued refinements of certain operational parameters of the machinery, e.g., the ability for operators to adjust the pressure needed to force crushed poultry bones with adhering muscle and other tissues through screens to separate muscle and other tissues from bone, and the size of the apertures in the screens and sieves through which the crushed bones, muscle, and other tissues are pushed under high pressure. These improvements have resulted in the ability to easily achieve bone content limits or decrease the bone solids that are a result of the mechanical separation process to less than the one percent reflected in the current poultry products regulations (9 CFR 381.117(d)).

In 1969, the Agency amended the regulations for poultry and poultry products inspection to, among other things, provide labeling requirements for boneless poultry products, as well as a prescribed bone solids content of not more than 1 percent (34 FR 13991). This limit was based on an evaluation conducted by FSIS of the operating results in a series of poultry establishments that used mechanical deboning equipment. Analyses were made of 485 samples of raw, mechanically deboned product from nine commercial operations that used the three types of machines most often used in the process. The analyses showed that the equipment, at that time, could be operated under commercial conditions to produce boneless poultry that contained no more than 1 percent bone solids, on a raw weight basis, and FSIS concluded that it was demonstrated that it was practical to limit the bone content in deboned poultry to 1 percent. Moreover, it was deemed that the one percent maximum bone solids content represents good manufacturing practices and reflects mechanical separation processes that are in control.

In light of the improvements that have occurred with regard to the machinery used to mechanically separate and remove most of the bone from the muscle and other tissues of poultry carcasses and parts of carcasses, FSIS recently conducted a study of the bone solids content of MSP.[4] The percentage of bone solids content (determined by calcium analysis) in boneless poultry products produced by mechanical separation processes was collected from approximately 50 establishments during August 1993, and represented a sampling of over 2000 products. The data indicate that the mean bone solids content of the samples of these products was approximately 0.6 percent; generally, half of the samples were above 0.6 percent (but below 1 percent) and half were below 0.6 percent.

V. RTI Study

In response to complaints from industry, some of them longstanding, that the Agency is ''not regulating meat and poultry equitably,'' FSIS contracted out to the Research Triangle Institute (RTI) a comparison of the meat and poultry inspection regulations. RTI found many differences in the two sets of regulations and narrowed down to 12 the areas of the regulations where significant differences exist.[5] FSIS has studied these areas to determine whether, in the actual conduct of inspection, they result in an inequitable application of the inspection laws, and, if so, what might be done to mitigate the inequities.

Among the areas identified in the RTI study is mechanically separated product. It notes that regulations exist on the use of MSM, but not on the use of mechanically separated poultry. The RTI study concluded that, in general, ''the regulations covering meat and poultry have been designed with the same intent—to protect 'the health and welfare of consumers by assuring that meat and meat food products [or poultry products] are wholesome, not adulterated, and properly marked, labeled, and packaged' (21 U.S.C. 602 and 451). Although the intent of the regulations remains the same, the actual requirements are quite different.'' The study further concludes that the bases for no comparable regulation for mechanically separated poultry are ''unfavorable consumer perceptions and court decisions resulting in label and use restrictions for MSM; poultry has no definitional requirements (e.g., it can be defined as 'chicken' or 'turkey').''

Mechanically separated meat (i.e., beef or pork) product became the subject of consumer criticism in the mid-l970's after USDA proposed to allow its use as ingredients in meat products and to allow it to be labeled as meat (i.e., ''beef'' or ''pork''). USDA also issued an interim rule that included standards for the use of mechanically separated red meat product. A lawsuit soon followed in which the Court found that this product is not ''meat'' as traditionally defined in the Federal Meat Inspection Act regulations. The Court further found that USDA had not considered adequately the health and safety effects of the mechanically separated red meat product.

To respond to questions on health and safety raised by the Court, a panel of government scientists was convened to examine the questions. The panel found that scientific studies established no unique health risks associated with mechanically separated red meat product, but that the product is

[3] Information provided by industry is available for public inspection at the FSIS Docket Clerk's Office.

[4] Data available for public inspection at the FSIS Docket Clerk's Office.

[5] A copy of the RTI study is available for public inspection in the FSIS Docket Clerk's office.

sufficiently different from muscle tissue meat in composition to require separate labeling. The panel recommended, among other things, that usage limitations be placed on this product.[6]

The panel reports, among other things, led FSIS to issue final regulations on June 20, 1978, that established preparation, composition, usage, and labeling requirements for mechanically separated red meat product, which was named mechanically processed species product (MP(S)P) and required that it be produced only under a quality control program approved by the Agency (43 FR 26416). This rule established a definition and standard of identity for this product that necessitated it being listed separately from meat in the ingredients statement of a product in which it was used. In 1981, the Agency proposed that this product be distinctly identified as ''mechanically separated (species) (MS(S))'' (where ''species'' refers to beef, pork, or other species of livestock) based on data, information, and arguments accumulated by and submitted to FSIS since the regulations for the product were originally promulgated on June 20, 1978 (46 FR 39274). FSIS proposed to amend the definition and standard for MP(S)P by deleting the term ''product'' from the product name and by considering terminology such as ''mechanically separated,'' ''mechanically deboned,'' and ''mechanically recovered'' as an alternative to ''mechanically processed'' to continue distinguishing the product from ''meat.'' Comments on the proposal indicated that the term ''mechanically separated'' was more descriptive of the product than the other terms listed in the proposal, that it was favored because of its use in other countries and adoption by the Codex Alimentarius Committee on Processed Meat and Poultry Products (1978), and that it did not have negative connotations associated with the other terms. Some commenters on the proposal stated that the term was truthful and understandable. Additional rulemaking on June 29, 1982 (47 FR 28214), reaffirmed the Agency's position that the product is not ''meat'' as traditionally defined, and that ''mechanically separated (species) (MS(S))'' is the name that will provide a more meaningful and concise description of the product's characteristics than ''mechanically processed (species) product.''

During this same period, mechanically separated poultry underwent product development separately from mechanically separated red meat product without similar FSIS regulations. Early distinctions in regulatory treatment were largely due to historical differences in how the two industries used these products and the way in which they came to public attention. One significant difference is that mechanically separated red meat product was being considered for use in products that had previously contained muscle meat. The use of mechanically separated poultry in poultry hot-dogs created less controversy because poultry hot-dogs, bologna, and similar products did not exist before they were made with mechanically separated poultry. Thus, consumers had no prior expectations about the formulation.

Differences in regulatory treatment of MSM and mechanically separated poultry have continued since that time. The meat industry claims that the effect of those differences has been a reluctance on the part of processors to use MSM, while MSP use has expanded. In response to the early rulemakings on MSM, the meat industry claimed that consumers would not buy products if ''mechanically separated beef (or pork, or other livestock species)'' is listed on the label. Similarly, in responding to the March 1994 advance notice of proposed rulemaking (ANPR) on MSP (discussed later in this document), the poultry industry claimed that, if they had to label MSP as a poultry ingredient, consumers would be misled into thinking that they are purchasing products inferior to what they have historically purchased or that the product has changed.

The Agency's regulation on the use of MSM and the absence of regulation on the use of mechanically separated poultry have raised two major policy issues. The first is whether current regulations are adequately protecting consumers. The second is whether different regulatory treatment for these similar products is justified. FSIS is not promulgating this regulation merely because of the current differences in the regulatory treatment of mechanically separated poultry and MSM, but rather because one of the basic statutory missions of the Federal Meat Inspection Act, under which MSM, such as ''mechanically separated beef (or pork),'' is regulated, and of the Poultry Products Inspection Act (PPIA), under which MSP is regulated, is to assure that products bear labeling that is truthful and not misleading. Here, for MSP, as FSIS did for MSM, FSIS has determined that a standard of identity and composition is needed for this product, along with an ingredient labeling requirement, and other requirements in order to carry out one of the statutory missions of the PPIA, as has been done in regard to the FMIA for MSM, by assuring that consumers are accurately informed about the ingredients of products they purchase, which in this case is an ingredient whose form and consistency materially differ from those of other boneless poultry products produced by hand-deboning.

VI. Advance Notices of Proposed Rulemaking

On June 15, 1993, FSIS published an advance notice of proposed rulemaking (ANPR) (58 FR 33040) soliciting comments, information, scientific data, and recommendations regarding the need for labeling of poultry product produced by mechanical separation and products in which such poultry product is used. FSIS received 2744 comments in response to the ANPR, most of which were general reactions to labeling issues. The majority of commenters responded to whether there was a need to identify mechanically separated poultry in the ingredients statement on the labels of meat and poultry products in which it is used as an ingredient. Roughly half the commenters supported identifying mechanically separated poultry in the ingredients statement because, the commenters stated that, among other things, consumers have ''a right to know'' it is an ingredient. The majority of the other commenters did not support identifying mechanically separated poultry in the ingredients statement, citing, in part, their belief that current policies are satisfactory and that labeling MSP would mislead consumers into thinking that they are purchasing products that are inferior or different than the product they have historically purchased. FSIS concluded that there is a ''truth-in-labeling'' issue that is founded in the mandate under which the Agency operates, viz., protecting consumers from misbranded poultry and meat products.

Subsequently, on March 3, 1994, FSIS published another ANPR (59 FR 10230), which solicited comments and information from the meat and poultry industries and industry-related organizations, the scientific community, academia, consumers and consumer groups, and other interested parties. FSIS sought comments on its tentative positions regarding defining and standardizing, or establishing other

[6] The panel's conclusions and recommendations were published in reports titled ''Health and Safety Aspects of the Use of Mechanically Deboned Meat, Volume I—Final Report and Recommendations, Select Panel'' and ''Health and Safety Aspects of the Use of Mechanically Deboned Meat, Volume II—Background Materials and Details of Data.'' These reports are available for public review in the FSIS Docket Clerk's office.

requirements for poultry products produced by mechanical separation, including possible provisions for the composition, characteristics, and use of such products, and requirements for manufacturing and labeling such products. In the March 1994 ANPR, FSIS considered, among other things, that certain poultry products produced by mechanical separation, i.e., those with greater than 0.6 percent bone solids content, but no more than 1 percent bone solids content, be separately identified on the labels of products in which they are used as ingredients by a distinct name. However, because of the improvements that were previously discussed in separating and removing the bone from skeletal muscle and other edible tissues of poultry carcasses and parts of carcasses, FSIS considered that some poultry products derived from mechanical separation machinery, i.e., those with 0.6 percent or less bone solids, be identified on the label of products in which they are used as poultry or poultry meat, e.g., ''chicken'' and ''turkey meat.''

FSIS received 106 comments in response to the March 1994 ANPR. The majority of the comments did not support the ANPR. The commenters strongly disagreed with the tentative position that only product with 0.6 percent or less bone solids content could be labeled ''(Kind)'' or ''(Kind) meat,'' without the reference to ''mechanically separated.'' The commenters also disagreed with the need for handling requirements, protein quality requirements, and quality control for boneless poultry products produced by mechanical separation. Further, commenters disagreed with establishing a minimum protein content and a maximum fat content requirement for poultry product produced by mechanical separation with greater than 0.6 percent bone solids content. They also disagreed with restricting the bone particle size to a maximum of less than 1.5 millimeter (mm) in the greatest dimension and limiting the use of mechanically separated poultry when used as an ingredient in other products. Many commenters stated that FSIS should continue allowing the declaration of mechanically separated poultry on product labeling as ''(Kind)'' or ''(Kind) meat'' (i.e., ''chicken,'' ''chicken meat,'' ''turkey,'' and ''turkey meat'') when it is used as an ingredient in poultry or meat food products.

FSIS generally agreed with the commenters with regard to protein quality, and protein and fat contents, and concluded that the tentative positions on protein quality, and minimum protein and maximum fat contents were unnecessary. Protein quality is not a health issue today, and information regarding protein and fat contents is generally available on the Nutrition Facts panel on most processed foods where mechanically separated poultry might be used as an ingredient. Furthermore, it was decided that the positions on quality control and handling requirements would be better addressed as part of larger regulatory efforts that were planned to consider ways of reducing the potential for situations that would render any poultry or meat food product adulterated, unwholesome, and/or misbranded. Therefore, the Agency concluded that it was premature to address the need for mandatory quality control or handling requirements for this one distinct category of poultry product. However, the Agency was not in agreement with the commenters on the other issues raised in the ANPR.

The Agency maintained that a bone solids content requirement is necessary because one of the characteristics that distinguishes mechanically separated poultry from hand-deboned poultry is the method of mechanical processing that results in a product which is safe in terms of composition, but one in which there is greater potential for the incorporation of powdered bone. The bone solids content of MSP is a direct result of the manufacturing process which involves the crushing of starting materials which consist of skeletal frames and carcass shells on which bits and pieces of muscle and other edible tissue remain after most of the muscle and other tissues have been removed by hand. Thus, there is the need for controlling the process of incorporating powdered bone into MSP so that it does not exceed the level of one percent which is considered a ''good manufacturing practice.'' The other distinguishing features that make mechanically separated poultry different than hand-deboned poultry are physical form and consistency. Informing consumers of such differences by a distinct and separate labeling of the presence of mechanically separated poultry in products in which it is used, is supported by the statutory responsibility of FSIS to assure that all labels on poultry and meat food products are accurate and not false or misleading.

The Agency did agree that its tentative labeling approach to identifying two types of mechanically separated poultry, based on the level of bone solids, i.e., above or below 0.6 percent, which was suggested in its March 1994 ANPR, appear to be in conflict. The mechanical separation process results in a product that is materially different than hand-deboned poultry in terms of its paste-like form and batter-like consistency, regardless of the level of bone solids present. The Agency tentatively concluded, after further review of the approach presented in the March 1994 ANPR and the comments received in response to it (and the prior June 15, 1993, ANPR), that continuation of the present labeling policy, even for those finished products with mechanically separated poultry that has a bone solids content of less than 0.6 percent, does not inform the consumer that these products contain the distinct ingredient mechanically separated poultry and that this may result in misleading labeling. The Agency also maintained that there is a need for bone particle size restrictions to augment the measurement of bone solids content as an assurance that mechanical separation processes are operating under good manufacturing practices that prevent the inclusion of unacceptable large fragments in mechanically separated poultry. The Agency also believed that in order to show that the process of manufacturing MSP was in control, i.e., operating under good manufacturing practices, records should be kept.

The Agency disagreed with commenters' objections to the tentative positions taken in the March 1994 ANPR on restricting the uses of mechanically separated poultry as an ingredient in certain products, e.g., in baby foods where there was a potential health effect associated with fluoride in mechanically separated poultry made from fowl, and where the textural characteristics of mechanically separated poultry altered the basic nature of the product to which it may be added, such as products represented as being composed of whole muscle. FSIS maintained the position that such restrictions were necessary for health reasons (in the case of the fluoride issue) or to protect the consumer from misleading labeling.

The Agency's positions on these major issues led to the publication of the December 6, 1994 proposed rule.

VII. Proposed Rule

On December 6, 1994, FSIS published a proposed rule to amend the Federal meat and poultry products inspection regulations to define and standardize, and establish other requirements for poultry products produced by mechanical separation, including provisions for the composition and use of such products, and requirements for manufacturing and labeling such

products (59 FR 62629). The proposal prescribed a definition and standard of identity for poultry products produced by mechanical separation with 1 percent or less bone solids content, that required compliance with certain criteria, e.g., bone solids content (measured as calcium content) and bone particle size. The proposal also provided recordkeeping and labeling requirements, and limitations on use of poultry products produced by mechanical separation.

A. Product Definition and Standard

FSIS proposed to prescribe a definition and standard of identity and composition for the poultry product with a paste-like form and batter-like consistency that results from the mechanical separation of and removal of most of the bone from attached skeletal muscle and other tissue of poultry carcasses and parts of carcasses which has a bone solids content of 1 percent or less. This product is commonly known in the poultry industry as mechanically separated or deboned poultry.

FSIS proposed that the boneless poultry products regulations described in 9 CFR 381.117(d) no longer apply to MSP. FSIS indicated that the current restriction on bone solids content in this regulation, as enforced by limiting calcium content, would be included with other compositional requirements in an MSP standard. Moreover, as a standardized product, MSP would be differentiated from other poultry product ingredients and it would be designated in the ingredients statements on finished product labels by the name specified in its definition and standard, in accordance with 9 CFR 317.2(c)(2) and (f)(1) and 381.118(a). Product failing to meet the bone solids content or bone particle size restrictions of the standard must be labeled as ''Mechanically Separated (Kind) For Further Processing'' and may only be used in producing poultry extractives, including fats, stocks, and broths because the manufacturing process completely removes the bone solids and bone particles.

1. *Product name.* FSIS proposed to define the standardized product that results from the mechanical separation and removal of most of the bone from poultry carcasses and parts of carcasses by a distinctive name. FSIS proposed that such product be called ''mechanically separated chicken'' or ''mechanically separated turkey,'' for example. FSIS indicated that this product differs significantly from boneless poultry products produced by traditional hand-deboning techniques in its spread-like form and consistency such that it should be regulated as a separate, standardized ingredient. FSIS indicated that it would welcome comments on other names that accurately reflected the process from which this product was derived, as well as its form and consistency.

2. *Bone solids content.* FSIS proposed that the definition and standard for MSP incorporate the existing restriction on the bone solids content of mechanically separated poultry products of not more than 1 percent (9 CFR 381.117(d)). FSIS also proposed that the definition and standard include maximum calcium content levels of not more than 0.235 percent in product made from turkeys or mature chickens or 0.175 percent in product made from other poultry, as a measure of bone solids content based on the weight of product that has not been heat treated.

3. *Bone particle size.* FSIS proposed that at least 98 percent of the bone particles present in MSP be restricted to a maximum size no greater than 1.5 millimeters (mm) in their greatest dimension and that no bone particles could be larger than 2.0 millimeters in their greatest dimension.

4. *Recordkeeping.* FSIS also proposed that establishments that manufactured MSP maintain records of bone solids content and bone particle size as a measure of process control. These records had to be made available to the inspector and any other duly authorized representative of the Secretary upon request.

B. Limitations on Use

FSIS proposed certain limitations with respect to the use of MSP in the formulation of poultry and meat food products. FSIS proposed such restrictions based on the potential fluoride contribution of MSP made from fowl (i.e., mature female chickens) and the characteristics of MSP, including the kind of poultry from which it is made and its form and consistency. FSIS also proposed that MSP may be used, except in certain cases, in any product defined by regulatory standards or Agency policies whereby ''(Kind)'' or ''(Kind) Meat'' (e.g., ''turkey,'' ''turkey meat'') are being used, provided that it is identified as ''Mechanically Separated (Kind)'' and conforms to requirements regarding the presence of skin within natural proportions (9 CFR 381.117(d)).

1. *Kind of product limitation.* FSIS proposed that when a poultry product is required to be prepared from a particular kind or kinds of poultry, (e.g., chicken), use of MSP of any other kind (e.g., mechanically separated turkey), would not be permitted. This provision assures that the kind of MSP used in a poultry product, such as mechanically separated chicken, is the same kind as is represented in the product name or other labeling. For example, product named ''chicken bologna'' could not be composed of mechanically separated turkey because such action could, among other things, result in false or misleading labeling by implying that the bologna was made with a chicken ingredient, when, in fact, it contained a turkey ingredient.

2. *Limitations on product made from fowl.* FSIS proposed that the use of mechanically separated chicken made, in whole or in part, from fowl (i.e., mature female chickens, as defined in 9 CFR 381.170(a)(1)(vi)) not be permitted in baby, junior, or toddler foods. The Agency based these restrictions on the potential fluoride contribution of product made from fowl to dietary intakes of young children.

The Agency noted that this position was supported by the 1979 Report, which was the best data available. FSIS recognized, however, that views on fluoride consumption have changed in the last few years, and in particular, recent views on the benefits of fluoride in the diet, including the diets of children. Comments were invited on this issue that would have an impact on the current validity of the proposed restriction on use of MSP from fowl .

3. *Poultry product limitations.* FSIS proposed that MSP not be allowed in poultry products that are composed of whole poultry muscle, and expected to be as such by consumers, except that it may be used for binding purposes at a level that is sufficient for purpose. However, FSIS would allow MSP in the sauce portion or any dressing of poultry products.

FSIS also proposed that MSP not be permitted in poultry products that have been processed only to the extent of cutting or grinding because it considers its use to be inconsistent with the basic whole-muscle character associated with such products. The Agency also would not permit MSP to be used in poultry products that are processed, convenience versions of ready-to-cook poultry or cuts or solid pieces of poultry or poultry meat for the reason stated above.

FSIS proposed no restrictions on the amount of MSP that can be used in poultry products, or meat food products, in which it is a permitted ingredient. However, prevailing standards of identity and composition for particular products may contain quantitative limits (e.g., a limit on the amount of poultry product ingredients permitted in cooked sausages such as frankfurters

and bologna (9 CFR 319.180)) or other restrictions on the quantity of various poultry product ingredients.

C. Labeling

FSIS proposed special provisions for the labels of MSP. If adopted, these provisions would supplement other, more general requirements for such labels (see 9 CFR parts 317 and 381, subpart N). The provisions are discussed below.

1. *The product.* FSIS proposed the following labeling provisions for MSP: (1) the name of the product (e.g., ''Mechanically Separated (Kind)'' (where ''kind'' refers to chicken, turkey, or other poultry) must be followed immediately by the phrase(s) ''made from fowl'' unless it is not made, in whole or part, from mature female chickens, and ''with excess skin'' unless it is made from poultry product that does not include skin in excess of the natural proportion present on the whole carcass; and (2) there must be appropriate descriptive terminology in the labeling of MSP if heat treatment has been used in the preparation of such product, e.g., ''cooked.'' Because the characteristics described in (1) and (2) above are ones which would affect the use of MSP, FSIS proposed that, in order to assure compliance with regulatory requirements and thereby prevent the adulteration and misbranding of finished poultry products and meat food products, such characteristics had to be clearly identified on the label of MSP when MSP left the establishment at which it was manufactured.

2. *Finished poultry products and meat food products.* FSIS proposed that the standardized paste-like product that results from the mechanical separation and removal of most of the bone from the skeletal muscle and other edible tissue of poultry carcasses and parts of carcasses be defined by its own name, e.g., ''Mechanically Separated (Kind),'' which would be declared in the ingredients statements on finished product labels by the name specified in its definition and standard.

VIII. Discussion of Comments

FSIS received 2420 comments in response to its December 6, 1994, proposed rule. The majority of the comments (over 95 percent) were submitted by individuals and food manufacturers and distributors; a few (less than 5 percent) were submitted by trade associations, consumer advocate organizations, academia, developers of machinery, food retailers, food consultants, law firms, an agency of the Federal government, and a foreign government. The majority of the comments related to product name. The comments are summarized below.

A. Product Definition and Standard Product Name

Nearly all of the comments were in response to the proposed requirement regarding the product name for MSP which established a distinct name for this product, mechanically separated (kind), where ''kind'' represents the kind of poultry, such as chicken or turkey, from which the product was made. Of these, roughly one-quarter agreed with defining the product by the distinctive name of ''Mechanically Separated (Kind) (MS(K)).'' Most of the commenters supporting the proposal stated that MSP is different from hand-deboned poultry and the product label should inform consumers of which type product they are getting. Further, the commenters asserted that ''they have a right to know'' if mechanically separated poultry is being used because mechanically separated poultry ''has more bone particles, calcium, and cholesterol'' (than hand-deboned poultry) because of the way it is processed. The commenters said that if the name is not changed to MSP, i.e., mechanically separated (kind), consumers might think that they are getting a product that has no bone particles and is identical to hand-deboned poultry. Several commenters also suggested that it is unfair for FSIS to treat mechanically separated poultry differently than mechanically separated meat with regard to its labeling and that this proposed rule will create parity between the poultry and red meat industries.

The majority of the other commenters disagreed with the proposed position to define the product by the name MSP. The commenters stated that: (1) Poultry that is mechanically deboned is the same as any other poultry and should be treated and labeled like any other poultry, i.e., hand-deboned; (2) current labeling is truthful and accurate, unlike the term ''mechanically separated,'' which suggests it is different because mechanical equipment is used; (3) labeling MSP differently than it is currently labeled will confuse and mislead consumers into believing that the product has undergone a change and is somehow different; (4) the proposed labeling terminology will force manufacturers to undertake numerous unnecessary product reformulations and promote new labeling nomenclature that is both unappealing and unnatural in context; (5) the common or usual name of finely ground turkey or chicken is ''turkey or chicken,'' by virtue of consistent, widespread and long-term usage of the term by the industry; (6) the addition of the words ''mechanically separated'' to the ingredients statement unnecessarily contributes to the general cluttering of limited label space; (7) ingredient labeling should be based upon product characteristics not on the manufacturing method, because most, if not all, ingredients in all food products are mechanically processed at some point, e.g., ''pitted cherries are mechanically pitted but do not require mechanically pitted on the label'' or ''orange juice squeezed by a machine is not required to be labeled as mechanically squeezed orange juice;'' and (8) the term will frustrate technological innovation by establishing a false dichotomy between mechanical and ''natural'' processes.

Commenters also suggested that any further regulation or change of ingredient declaration for this product is unnecessary and not based on consumer expectations or scientific determination. Commenters stated that there is no adequate justification for setting a new standard of identity for this product. They stated that FSIS has not provided any research, consumer studies, or marketing data to support the need for this labeling change and that no new evidence has been presented by FSIS to refute that mechanically separated poultry is materially the same as poultry derived from hand-deboning. Commenters also questioned placing additional requirements on a product that is already accepted by consumers. Another commenter stated that the only reason FSIS was initiating a change to the name for MSP was because of the lawsuit by the red meat sausage manufacturers (i.e., *Bob Evans Farm, Inc. et al.,* v. *Espy*).

Further, one commenter alleged that the reason given by FSIS for proposing this rule, which is to prevent mislabeling of products and misleading consumers, is invalid. This commenter was the only one to offer consumer data[7] regarding consumer reactions to labeling MSP. The commenter contracted out a consumer study to measure consumers' preferences for the terms ''chicken,'' ''turkey,'' ''mechanically separated chicken or turkey,'' and ''finely ground chicken or turkey.'' The commenter concluded that the consumer research shows that ''the majority of consumers consistently report no preference to change from current labeling practices.'' According to the commenter, ''less than 2 in 10

[7] Comment submitted by the National Turkey Federation is available for public review at the FSIS Docket Clerk's office.

consumers in their study expressed the opinion that 'mechanically separated' is an appropriate labeling term for comminuted poultry,'' and that, if a change is made to current policies, ''finely ground'' would be a more preferred term. The commenter concluded that the results of the research were applicable to consumers in general. Several other commenters cited the consumer research presented by this commenter and also asserted that, if any change is made with respect to the product name, ''finely ground (Kind)'' is much more informative than ''MSP.'' Other commenters suggested other names such as ''ground,'' ''finely textured,'' and ''finely comminuted'' poultry.

FSIS has concluded that the name mechanically separated poultry, i.e., ''mechanically separated (kind of poultry) (MSP)'' (e.g., mechanically separated chicken) should be adopted as the product name and that a separate standard of identity should be established for this product to reflect its name and set forth appropriate parameters for the product. FSIS has determined that the name ''mechanically separated (kind of poultry)'' is an appropriate, nonmisleading name for this product based on comments received in this rulemaking, an examination of the process by which MSP is made, the distinct paste-like form and batter-like consistency of MSP, the need to distinguish MSP's differences from hand-deboned poultry on labeling to comply with FSIS' statutory consumer protection responsibilities to assure that labels of meat and poultry products are accurate, and a review of product name issues raised in the rulemaking for mechanically separated meat, a red meat product produced in a mechanical manner similar to MSP.

As will be discussed more fully below, FSIS does not agree with various assertions of some commenters that establishing the name MSP for this product is unnecessary and unjustified. The name mechanically separated (kind of poultry)'' clearly and precisely describes the manner by which the product is made. The process by which MSP is made along with the type of starting materials used to make it, which contain only bits and pieces of muscle tissue and other edible tissues, such as skin and fat, are what causes this product to be different from hand-deboned poultry. Consumers will be misled if they are not informed that this product is materially different from hand-deboned poultry, and the appropriate way to inform them of this difference is to establish a name for MSP that distinguishes it from hand-deboned poultry. As FSIS recognized in its rulemaking on MSM, the ability of any name to convey in only a few words the nature of a product is limited. However, FSIS has determined that the term MSP will appropriately notify consumers that the product they are purchasing contains a distinct ingredient that results from the mechanical separation process.

FSIS received various comments that suggested alternative names for the product, if it was concluded that more descriptive labeling was necessary, such as ''ground (kind of poultry),'' ''finely ground (kind of poultry),'' ''comminuted (kind of poultry),'' and ''finely textured (kind of poultry).'' FSIS has concluded that these names do not provide a concise and accurate description of the product because the usage of the terms is not unique to MSP, and these terms convey the impression that the product has the same form and consistency as product with defined particles of meat, skin, and fat, rather than, as here, one that has a paste and batter-like consistency. FSIS has concluded here, as it did for its previous rulemaking on MSM (47 FR 28214, 28224), a similar product produced by a mechanical separation process that has a paste and batter-like consistency, that the name of the product should include the term ''mechanically'' to indicate the nature of the process used in making the product. When FSIS adopted the name ''mechanically separated'' in its 1982 rulemaking on MSM to describe mechanically separated livestock product such as ''beef'' or ''pork,'' the adoption of this name was challenged in a lawsuit. The name was upheld by the Courts in *Community Nutrition Institute (CNI)* v. *Block*, No. 82–2009 (D.D.C. Dec. 1, 1982), aff'd 749 F.2nd 50 (D.C. Cir. 1984). As also has been previously noted, the term ''mechanically separated'' is recognized internationally by the Codex Alimentarius Commission of the United Nations and by individual countries that trade with the United States.

In its proposed rule, FSIS proposed the term ''Mechanically Separated'' (Kind) for MSP. As a point of clarification, FSIS would like to make it clear that ''kind'' refers to the ''kind of poultry,'' such as chicken, turkey, etc., used in a product. FSIS feels that the name for this ingredient should be clear about this fact, and, therefore, has clarified its regulations to reflect this fact.

FSIS also wishes to clarify the scope of its definition and standard for MSP. As with FSIS' definition and standard for MSM, the standard and definition for MSP are intended to only cover the product with a paste-like form and batter-like consistency manufactured by machinery that operates on the differing resistance of hard bone and soft tissue to pass through small openings, whether it employs sieves, screens, or other devices or whether or not bones are pre-broken before being fed into such equipment. This regulation, however, is not intended to cover whole pieces of muscles that are mechanically separated from poultry carcasses or parts of carcasses. FSIS has clarified its regulation in this regard by indicating that the product that FSIS is regulating is the one that results from the mechanical separation process that has a paste-like form.

In response to the commenters who suggested that there is no difference between MSP and hand-deboned poultry and, that therefore, they should be labeled the same, FSIS disagrees with this comment. The method of obtaining poultry products by the mechanical separation process results in a product whose form and consistency materially differ from that of poultry derived by traditional hand-deboning methods.

MSP is a poultry product that results from the mechanical separation and removal of most of the bone from the skeletal muscle and other edible tissues, such as skin with attached fat, of poultry carcasses and parts of carcasses. The process of manufacturing MSP begins with starting materials from which most of the muscle and other tissue has already been removed by hand, on which only bits and pieces of tissue remain. The process involves the crushing of the bones (i.e., the starting material) with adhering tissue and the removal of the bone using high pressure which forces the mass of tissue through holes in the equipment, allowing a small amount of powdered bone to pass along with the edible tissue. This results in a product with a paste-like form and cake batter-like consistency, that no longer resembles ''chicken'' or ''turkey.'' The rigors of the mechanical separation process alter the structure of the muscle fibers, skin, fat, and other tissues of the starting materials so that they become a blended and amorphous paste-like mass that is no longer recognizable as ''chicken'' or ''turkey.'' On the other hand, ''hand-deboned poultry'' is a boneless poultry product that is a result of removing whole muscle and other edible tissue (e.g., skin with attached fat) from poultry carcasses and parts of carcasses, using hand-deboning methods, e.g., hand-held knives. Such product is easily recognized as the kind of boneless muscle and tissue that would be gotten by a person who used

a knife in their own kitchen to cut off pieces from a poultry carcass or parts of poultry, such as drumsticks, thighs, and breasts, because there is not a substantial disruption of the physical form of the product by hand-deboning. With hand-deboning, the muscle fibers are visible and maintain much of their original configuration. Understandably, hand-deboned muscle and other tissue may be subsequently processed through a grinder, flaking machine, or dicer to yield poultry in ground, flaked, or diced form, but such product still exhibits a physical character associated with ''chicken'' and ''turkey,'' rather than a cake batter. This is because the rigors of these processes which occur after hand-removal of muscle and other tissue do not alter the physical nature of the tissues to the degree that mechanical separation does.

In response to the comments regarding consumers being confused or misled by labeling MSP differently than is currently labeled, i.e., as ''chicken'' or ''turkey,'' the Agency is not aware of reliable or conclusive data that support the assertion that consumers will be confused or will believe that the products in which MSP has been used are different from the products they purchase after the final rule is effective. The Agency does not agree with one commenter's assertion, the American Meat Institute, that a report of a study it submitted [8] on an evaluation of mechanically separated red meat issues support its view that the required labeling for MSP has ''a great affirmative potential to mislead.'' The report cannot be relied upon as support for this conclusion for a number of reasons, including the following discussed here. The report indicates it used focus group sessions to, among other things, explore consumer reaction to and understanding of the term ''mechanically separated meat.'' As noted previously, MSM is a red meat product produced by a mechanical separation process similar to that by which MSP is made. However, very little of this product has been made and used in products with which consumers are familiar, and it is not surprising that consumers might not be aware of the product the term ''mechanically separated meat'' represented. Therefore, reactions to labels for products containing mechanically separated meat would not necessarily be applicable to the labels for mechanically separated poultry. Furthermore, as the study itself states, the focus group method used does not ''produce precise, absolute measures,'' ''its findings must be seen as hypotheses,'' and ''findings from focus group sessions are not projectable to a larger population.'' Moreover, the study also sought consumers' reactions to other labeling issues and the multiplicity of issues raised could bias the responses made to the mechanically separated meat labeling issue and, in turn, the validity of applying the finding to labeling of mechanically separated poultry.

In the Agency's opinion, the declaration of MSP as ''chicken'' or ''turkey,'' rather than by a distinctive name in the ingredients statement of a product in which it used, is misleading. ''Chicken'' and ''turkey'' are terms associated with boneless poultry products derived by hand from starting materials that consist of whole and half carcasses, and parts of carcasses, on which whole muscle and other edible tissues substantially exist. FSIS believes that MSP differs significantly from boneless poultry produced by hand-deboning techniques because of its paste-like form and batter-like consistency. The form and consistency of MSP is a direct result of the mechanical machinery (i.e., process) from which it is derived which involves the removal of bits and pieces of muscle tissue and other edible tissues from boned-out materials, i.e., skeletal frames and carcass shells. Therefore, FSIS has concluded that MSP should be regulated as a separate, standardized ingredient, and that the characteristics of this ingredient are sufficiently different from the characteristics of hand-deboned poultry that it should be identified on product labels in a way that distinguishes it from hand-deboned ingredients. Such labeling will help further inform consumers about the content of the products they are purchasing. FSIS believes that such a labeling requirement is necessary in order to fulfill its statutory responsibility under the FMIA and PPIA to protect consumers by assuring that the labels of poultry and meat food products are accurate and not false or misleading.

If the commenters believe that consumers will be misled into thinking that they are purchasing products that are different from what they have historically purchased or that the product has changed, the industry would have a full year before the rule becomes effective, to educate consumers that the products they will be purchasing that reflect the name MSP in the ingredients statement are what they have historically purchased. FSIS, itself, also believes it is important to inform consumers about this product. Therefore, it intends to review its public information program and incorporate into it appropriate explanatory material on the process used to make MSP, its characteristics, its wholesomeness, its safety, and its nutritional qualities. The Agency believes that consumers will be misled if mechanically separated poultry is not separately and distinctly listed as an ingredient, because of the differences previously discussed between it and hand-deboned poultry. The Agency's responsibility under its consumer protection mission is to assure that labeling information is accurate and helps consumers make informed food purchasing decisions.

In response to the comments that asserted that the requirement for labeling ''MSP'' will result in a need for manufacturers to reformulate products that currently contain MSP, and ''promote new labeling nomenclature that is both unappealing and unnatural in context,'' the Agency is not certain as to why such changes will be necessary. There were no reliable or conclusive data submitted in support of these comments that show a potential negative impact on poultry or meat food product formulations. It is the Agency's belief that MSP continues to be a wholesome and safe, low-cost source of protein, with nutritional attributes comparable to ''chicken'' and ''turkey.'' The paste-like form and batter-like consistency of MSP that results from the mechanical separation process provide unique functional characteristics that are a key benefit for its use in the variety of poultry and meat food products (especially emulsion-type products like hot dogs) in which it is currently used. This benefit seems likely to ensure continued use of the ingredient in products that are meeting the demands of consumers who purchase the products.

Further, in response to comments about a negative impact labeling will have on consumers' acceptance of products labeled with ''MSP,'' there were no persuasive arguments made that support this as an outcome. The majority of the comments that disagreed with the proposed identity of the products as ''MSP'' did not provide data, but offered opinions on the consumers' view of the proposed name. The data that were presented by the one commenter that pursued consumer research were not compelling because of shortcomings in the study design.

The report of consumer research submitted by the commenter tested consumer preferences for the terms ''mechanically separated,'' ''finely ground,'' and ''chicken'' and ''turkey,''

[8] A copy of the comment and the report are available for review in the FSIS Docket Clerk's office.

as names for MSP. The report concluded that the majority of consumers, if given the choice between names such as ''mechanically separated chicken or turkey,'' and ''turkey'' or ''chicken,'' preferred labeling to stay as it is, ''turkey'' or ''chicken.'' If, however, a change in the name is made, the report concluded that ''finely ground'' is overwhelmingly preferred to ''mechanically separated.'' The commenter concluded that the data show that a labeling change to ''mechanically separated'' is unjustified and that consumers gain no salient information from the use of such a term. They indicated that the data were gathered from consumers who were informed as to the Agency's concerns regarding the presence of ''powdered bone'' and a change in texture of finely comminuted poultry.

The survey data's conclusions were based upon 300 interviews of people in five states, who were given a questionnaire, after reading an informational handout. The commenter indicated that the survey participants had used cold cuts, luncheon meats, hot dogs, or smoked sausage, in the past three months, and were heads of households and primary or co-primary food purchasers between the ages of 21–69, 80% who were female and 20% who were men.

The Agency has reviewed the survey conducted by the commenter and has determined that the survey's findings are not reliable. The informational handout given to survey participants to read before they answered the survey questions did not tell those interviewed the following information which they needed to have in order to make informed responses to the questions posed to them: (1) a description of the difference between the form and consistency of MSP and hand deboned poultry; (2) descriptions of how the mechanical separation process works and what the product is like that comes from it; (3) a description of the difference in the nature of the starting materials for hand-deboned poultry and MSP, and (4) a clear idea of the types of products in which MSP is used. Further, the interviewees were not shown any samples of MSP and hand-deboned poultry and, thus, did not view these products and see the differences in form and consistency between the products.

Moreover, the content of the handout was slanted in the sense that it described only certain aspects of MSP and used confusing names for MSP which obscured the difference between MSP and hand deboned poultry, thus making any considered labeling change appear to be unnecessary. For example, the informational handout indicates that the way MSP is made is that ''new machinery was invented that could separate poultry meat from bone without the need of hand deboning.'' This, however, is only a partial description and is, thus, misleading. As has been previously stated in this docket, the new machinery does not completely separate meat from bone. Rather a small amount of powdered bone that results from the fact that the machines crush the bone of the starting materials from which the MSP is made, becomes mixed together with the other material, such as muscle tissue and skin removed from the starting materials. Another example is that the handout states that ''in either case,'' referring to MSP and hand deboned poultry, ''the original form of the poultry is changed when it is used as an ingredient in making hot dogs, bologna, and other processed meat.'' This is misleading because, as has been previously noted, MSP is an amorphous and paste-like mass that is not recognizable as bits and pieces of chicken and turkey, and even if hand-deboned chicken or turkey was further processed by grinding, it would still exhibit a physical character associated with chicken or turkey.

Moreover, the handout indicated that both mechanically separated and hand deboned poultry may contain up to 1% bone, and that the powdered bone in MSP ''provides nutritionally available calcium.'' However, whether the powdered bone in MSP provides a nutrient that consumers want has nothing to do with the issue of what the name should be of this product. Many types of products provide calcium but they are appropriately described by different names because they are distinct types of products. The handout also stated that ''in its raw, fresh form, consumers are familiar with ground turkey which may be made using the same equipment.'' This statement is misleading because the important aspect of the way the machinery operates to produce a product with a paste-like form and batter-like consistency is not presented.

Moreover, it is misleading to conclude that switching to the term ''mechanically separated'' would likely result in substantial decrease in consumption of this products, when the interviewees were not told that it was the distinct character of this product, rather than a question of the wholesomeness of the product, that was a basis for FSIS' proposed labeling change. Further, the interviewees also were not told that product made without MSP could possibly cost more to purchase than one made with MSP.

The conclusions reached by the commenter from the research are also not valid because the study design did not account for possible errors that may make the information gathered unreliable. The study used a mall intercept survey approach and involved soliciting reactions on the terms from 300 shoppers in shopping malls. The sample is not statistically representative of a national population because of the way the participants were selected. Although the commenter claimed that they have data from ''true consumers,'' the participants represent a population who happened to be able to shop in the mall, and on the day of the survey. A concern with the usefulness of the results stems from the non-probability, quota sampling approach. Non-probability samples do not permit an estimate of sampling error. With smaller samples, the range any reported percentage can take can be relatively large. Since a sample of 300 respondents is smaller than most national level consumer surveys, comparisons which look different may not be statistically different when inferred to the population of primary food buyers. For example, the difference between the 10 percent of respondents reporting they will probably buy more product labeled as ''finely ground'' versus the 6 percent that reported they will probably buy less could be due to sampling error. Additionally, the approach to sampling tends to under-represent persons who are difficult to contact or reluctant to participate. In this case, under representation of certain persons with different views is likely to yield underestimates of respondents who report that the issue is of no importance to them.

In response to the comments that stated that the term ''mechanically separated'' is misleading because it suggests the product is different because mechanical equipment is used, FSIS believes that the use of mechanical equipment is, in fact, the very reason MSP differs from hand-deboned poultry. The process of removing bits and pieces of edible muscle and other tissues from starting materials consisting of skeletal frames and shells is far different than the process of removing muscle and other tissue from bone by hand. The process of manufacturing MSP results in a paste-like product which no longer resembles the consumer's expectation of ''chicken'' or ''turkey.'' The examples provided by the commenter of other products that are ''mechanically'' processed, and which do not reflect this in their names, are not comparable

because the form and consistency of the products mentioned would not differ significantly whether the products were processed by hand or machine.

Therefore, the Agency believes that MSP accurately and concisely describes the poultry product produced by mechanical deboning, indicating the nature of the process by which and the kind of poultry from which it is made, and distinguishing it from poultry product ingredients produced by traditional hand-deboning techniques. The name includes ''(Kind of poultry)'' rather than ''poultry'' to make it clear that the kind of poultry (9 CFR 381.1(b)(40)) from which the product is made must be specified (e.g., ''Mechanically Separated Chicken'').

In response to comments that suggested the term ''mechanically separated'' will frustrate technological innovation by creating a false dichotomy between mechanical and ''natural'' processes, the Agency stresses that the mere application of the mechanical means of separating bone from muscle and other tissues does result in a materially different product than that which is derived by hand. The action of mechanical separation of bone from poultry tissue involves crushing bones on which bits and pieces of meat, skin, and fat remain after hand removal of the majority of edible tissue. The bones with adhering tissue are forced under high pressure through screens or sieves in the machinery to result in a paste-like and batter-like composite of tissues that had been adhering to the bones, that also contains a minute amount of powdered bone. The physical action of the mechanical process cannot be duplicated by hand-deboning methods to result in a similar product.

MSP has been referred to as ''Mechanically Separated'' Poultry within the meat and poultry industries to specify the form and derivation of the product. FSIS is aware that other descriptions have been associated with poultry product produced by mechanical separation, such as ''mechanically deboned'' poultry, ''finely ground'' poultry, and ''finely comminuted'' poultry. There are reasons why these other terms do not appropriately convey the identity of MSP.

FSIS believes that where a primary distinguishing characteristic of a standardized product is its bone content, it would be inappropriate to define it by a name that includes the term ''deboned'' and use of this term in labeling might mislead consumers by implying that such product contains no bone. This was also concluded in the final rule that defined and standardized MSM (47 FR 28214). Although consumer focus group research reported in the MSM proposed rule (46 FR 39274) suggested that consumers thought that ''mechanically deboned'' is a term that is more acceptable than ''mechanically processed,'' ''mechanically separated,'' and ''mechanically recovered,'' the Agency in its final rule for MSM rejected the term ''mechanically deboned'' in lieu of ''mechanically separated.'' The basis was that it was believed that ''mechanically deboned'' would incorrectly represent to consumers that the product does not contain bone.

With regard to other terms that refer to the form or consistency of poultry products, e.g., ''finely comminuted,'' ''comminuted,'' ''finely ground,'' ''ground,'' and ''finely textured,'' the Agency does not view such terms as truly reflective of the form and consistency of MSP. MSP is paste-like in form and like a cake-batter in consistency. When it emerges from the mechanical separation machinery, it is an amorphous blend of the tissues removed from the skeletal frames and shells that were the starting materials. The process uses high pressure and incorporates a minute amount of powdered bone into the product in the operation of removing bone from the tissue. Terms such as those mentioned are used to reflect products with a more defined particulate size and would be perceived that way by consumers, e.g., as products with a form and consistency comparable to ground beef. Additionally, terms such as ''comminuted'' are not readily understood by many consumers and only have a common usage and understanding among those involved in the meat and poultry industry. Terms such as ''finely ground'' and ''comminuted'' have also been used by industry interchangeably to describe ground poultry, i.e., poultry with defined muscle particles. Moreover, the terms cited above have been used indiscriminately to refer to MSP, and although they relate to form and consistency, do not sufficiently inform consumers that MSP is an ingredient in the products they purchase. Therefore, these terms are limited in their ability to effectively meet the Agency's communication objective of conveying distinctly the presence of MSP on the labels of products. Furthermore, there were not any comments received that offered other, novel terms that could be applied to MSP.

Regarding the comments that cited the long-term use of the terms ''chicken,'' ''turkey,'' etc., to refer to mechanically separated poultry, as the reason for not changing the name of MSP, the Agency has taken into account the information and experience acquired since the first regulatory action on MSP in 1969 and current regulatory policies, and has reviewed and reevaluated the existing regulations, particularly in light of the labeling issues. As a result of its review and reevaluation, the Agency has concluded that the distinct declaration of ''MSP'' is necessary after a careful review of (1) the process of manufacturing MSP which results in a product with a paste-like form and cake-batter-like consistency, (2) the characteristics (i.e., form and consistency) of MSP which are significantly different from those expected of ''chicken,'' ''turkey,'' etc., which are derived by hand-deboning, (3) the issues raised in rulemakings and court decisions that resulted in the distinct identity of the livestock product similar to MSP as ''MS(S),'' because (in part) of the form and consistency of that product, and (4) the statutory responsibilities to protect the public and prevent the preparation and distribution in commerce of poultry products and meat food products which are misbranded or not properly marked, labeled, or packaged.

Bone Solids Content

FSIS stated in the proposed rule that the definition and standard for MSP would incorporate the existing restriction on the bone solids content of mechanically separated poultry products of not more than 1 percent. All of the 26 commenters responding to this issue expressed strong support for restricting the bone solids content to no greater than 1 percent. After evaluating data on substances of potential concern that may tend to concentrate in bone, the 1979 report on health and safety aspects of the use of mechanically separated poultry did not recommend any change in the existing bone solids limit. FSIS continues to believe that the requirement of no more than one percent bone solids content is reflective of good manufacturing practices that result in wholesome and safe boneless poultry products.

Therefore, this final rule will restrict the bone solids content to no greater than 1 percent, as represented by calcium content to a maximum level of not more than 0.235 percent in product made from turkeys or mature chickens or 0.175 percent in product made from other poultry, as a measure of bone solids content based on the weight of uncooked product (i.e., product that has not been heat treated). The differences in the calcium value between turkeys and mature chickens, and the value for

other poultry, are attributable to the higher level of calcium found in turkey bones which are typically larger than other poultry bones, and due to more calcium being deposited over the lifetime of older chickens.

Bone Particle Size

Twenty-six commenters responded to the proposed bone particle size requirement which restricts at least 98 percent of bone particles to a maximum size no greater than 1.5 millimeters (mm) in their greatest dimension and allows no bone particles to be larger than 2.0 millimeters in their greatest dimension. About half of the 26 commenters supported the restriction of bone particle size. One of the commenters stated that the bone particle requirement provides consumers with sufficient protection from any hard bone particles and also, from any constituents which might not normally be found in items manufactured from muscle tissue using the traditional hand-deboning process.

The other half of the commenters opposed setting limits on bone particle size stating that for more than 20 years of use of MSP, bone particles have not been a significant problem. The commenters believe that the nature of the separation process itself, with the comminution of product which is pushed through screens under pressure, minimizes the likelihood of large bone particles. Furthermore, the relative softness of poultry bones due to their age and size make them unlikely to present a physical hazard. One commenter stated that the American Dental Association Health Foundation found no health problems associated with poultry bone particles and that the Michigan State University has reported no digestibility problems of issue. Other commenters cited the 1979 Report's conclusion that ''bone particles in MSP will not present any health hazard because of size or hardness, provided that bone particle size is controlled.'' Commenters also suggested that requiring standardized bone particle limitations will result in increased analytical costs to the processor without improving or otherwise positively effecting food safety. Other commenters pointed out that the proposed rule did not suggest a method by which bone particle testing can be conducted.

FSIS believes that a bone particle size limitation augments the bone solids content restriction and is a meaningful indicator of a mechanical separation operation that effectively removes bone from muscle and other tissue. The mechanical separation process involves bone crushing and screening out bone from soft tissue, thereby providing a mechanism for limiting the amount of bone in the product. The mechanism of separating bone from tissue does not necessarily make the remaining bone particles uniform in size. Bone is an unexpected ingredient and the process of mechanical separation should be operated to avoid the likelihood of large bone particles occurring. If bone were present in such a particle size as to be readily apparent to the taste or touch, it would be identifiable as bone and might be reason to consider the product adulterated. The 1979 Report recommended that bone particle size be controlled to ensure that equipment type or processing does not result in unacceptably large bone fragments in mechanically separated poultry. There were no new data submitted by commenters that refute the data in the 1979 Report and, thus, they appear to indicate the reasonable limits, i.e., good manufacturing practices, by which manufacturers are operating. FSIS agrees with the recommendation in the 1979 Report and is, therefore, requiring that at least 98 percent of the bone particles present in mechanically separated poultry have a maximum size no greater than 1.5 mm in their greatest dimension and that no bone particles be greater than 2.0 mm in their greatest dimension.

Recordkeeping of Calcium and Bone Particle Size

The proposed recordkeeping requirements required that manufacturers of MSP maintain records to support the fact that the MSP met the proposed bone solids content requirement for MSP and the proposed bone particle size requirement for this product. The majority of the comments received in response to this requirement supported the requirement. The commenters believed that establishments should maintain records of bone solids content and bone particle size because it assists in compliance and provides an incentive for good process control. A number of commenters argued that mandatory recordkeeping for bone particles would have operational costs associated with it, which are proven to be unnecessary, particularly in light of the fact that there is no food safety issue of concern.

FSIS has reconsidered the need for establishments' keeping records on bone solids content (measured as calcium) and bone particle size in light of the comments that stated that a recordkeeping requirement was unnecessary. The Agency wishes to be cooperative to ease burdens on industry, in appropriate situations, and allow flexibility in the manner in which requirements can be carried out, where it can do so and still carry out its statutory missions to prevent the distribution of adulterated and misbranded meat and poultry products. Consistent with this effort, the Agency in its proposal for MSP did not require the industry to either carry out any prescribed tests for bone solids content or bone particle size of the MSP produced, or to carry out any type or amount of sampling of the MSP produced. The agency has now concluded that removal of the recordkeeping requirement for bone solids content and bone particle size will appropriately allow producers even more flexibility in meeting these requirements. FSIS, of course, expects producers of MSP to comply with the bone solids content and bone particle size requirements, and it will implement spot checks in order to verify that such compliance is occurring by producers of MSP. If during these spot checks, or during any other inspection or compliance review, FSIS finds a problem, it believes, however, that any records producers have maintained in regard to compliance with these requirements, will be helpful to FSIS and, in turn, to the industry, in evaluating the company's control of bone solids content and bone particle size.

B. Use Limitations and Restrictions

Most of the commenters responding to the issue regarding limitations on the use of MSP disagreed with the Agency's position that limitations of use in products composed of whole muscle or of MSP made from fowl are needed. The commenters believe that there should be no limitations on use because there are no safety or health concerns regarding MSP. They also believe that use levels of MSP should not be restricted because the marketplace is a better judge of the quality of poultry products that are composed of MSP than FSIS. However, two commenters agreed in part with the proposed limitations. The two commenters agreed that where a poultry product is required to be prepared from a particular Kind or Kinds of poultry (e.g., chicken), use of MSP of any other kind (e.g., mechanically separated turkey) should not be permitted.

FSIS also received 11 comments regarding the fluoride content of MSP made from fowl and the use of MSP made from fowl in baby food. All of the commenters disagreed with the proposed limitation on the use of product made from fowl in baby foods because of potential health implications associated with over-consumption of

fluoride in infants' diets. One commenter stated that based on discussions with baby food companies, a local children's dentist, experts from Duke University Medical Center, the University of North Carolina School of Dentistry, and the American Academy of Pediatrics, there is not one known documented or suspected case of fluoride problems related to chicken in baby food. Furthermore, the commenter stated that these people had very encouraging remarks for the positive effects that fluoride from all food sources has had on the overall dental health of the children in our country.

FSIS continues to believe that the use of MSP should be limited in certain poultry products. In response to the commenters that said where a poultry product is required to be prepared from a particular kind or kinds of poultry (e.g., chicken), use of MSP of any other kind (e.g., mechanically separated turkey) should not be permitted, FSIS agrees. This provision assures that MSP made from a certain kind of poultry is not used in a poultry product represented as containing ingredients from a different kind or kinds of poultry, thus avoiding situations of misbranding.

The Agency however, agrees with comments on the proposed use restrictions of MSP in processed products composed of whole poultry muscle that suggested a restriction was unnecessary because the use of MSP in a product formulation is an issue of product quality. The Agency recognizes the increasing market popularity of convenient, ready-to-cook or ready-to-eat products that are composed of whole poultry muscle to which a portion of MSP is added. MSP benefits the manufacture of such products because it is batter-like and can be molded to form a desired product shape, and fill voids or spaces to make product shapes uniform. The level of use of MSP that is associated with these products exceeds the level that is used for strictly binding muscle pieces together—an allowance that was acknowledged in the proposal. The presence of MSP will be declared in the ingredients statement according to the requirements in this final rule. Therefore, regardless of the level of MSP used, consumers will have the information necessary to make an informed purchase decision.

The Agency is also keenly aware that with the allowance for the addition of MSP (and other highly comminuted boneless poultry products) to products composed of whole poultry muscle there is presented an issue regarding truthful and non-misleading product names. The names for these products should also convey to the consumer that the product is not composed of entirely intact, whole muscle, perhaps through the use of a qualifying statement. It is expected that the names for products composed of whole poultry muscle and portions of MSP, or other boneless, comminuted poultry, would reflect this fact in their names to make them truthful and accurate. The Agency will be assessing for possible future policy development the broad issue of the appropriate naming of products composed of MSP or other boneless poultry to convey to consumers that they are not composed of intact, whole muscle, as may be expected.

FSIS agrees with the commenters views that there is no need for a requirement that would impose restrictions based on the potential fluoride contribution of MSP made from fowl (i.e., mature female chickens). In the proposed rule, FSIS proposed restricting the use of MSP made from fowl in baby, junior, and toddler foods, citing its concern for the potential effect of fluorosis in the susceptible population of babies, infants, and toddlers. MSP made from fowl has higher amounts of fluoride because the bones of older female chickens contain more fluoride than younger chickens. In the proposal, the Agency cited the conclusions of the 1993 National Academy of Science's (NAS) Subcommittee on Health Effects of Ingested Fluoride (NAS Fluoride Report)[9] which indicated that the most effective approach to controlling the prevalence of dental fluorosis, without jeopardizing the benefits of fluoride to oral health, is likely to come from more judicious control of fluoride in foods, especially those items used by young children. The Agency requested that commenters provide any information that would either reaffirm or contradict the conclusions reached in the 1979 health and safety report regarding fluoride.

After reviewing the information submitted by commenters, and reevaluating the findings of the NAS Fluoride Report, FSIS no longer has a concern regarding the potential effect of fluorosis. Most noteworthy among the information FSIS considered in withdrawing the proposed limitation on MSP from fowl are reports of the changing sources of fluoride ingestion, the positive effects of increased fluoride intake on reduction of dental caries in the 1990's, and the decrease in the ingestion of fluoride from infant formulas since 1979. Therefore, FSIS will not impose a restriction on the use of MSP from fowl in baby, junior, or toddler foods. Because the Agency has concluded that MSP made from fowl should not be restricted in baby foods, there is no longer a need to require the labeling of MSP from fowl, as ''mechanically separated chicken, made from fowl,'' as proposed.

In addition, in response to comments seeking clarification on the uses of MSP, FSIS will not prohibit the use of MSP in cooked sausage products, such as frankfurters, franks, furter, hot dogs, vienna, bologna, garlic bologna, knockwurst, and similar products. The Agency will permit MSP to be used alone or in combination with poultry meat in cooked sausage products identified in 9 CFR 319.180, however, not in excess of 15 percent of the total ingredients, not including water. FSIS is amending 9 CFR 319.180 to allow for such use. FSIS inadvertently omitted such a provision in the proposed regulations.

C. Labeling

Commenters had varying opinions regarding the labeling of poultry product produced by mechanical separation as ''MSP.'' Of the 14 commenters responding to this issue, three stated that poultry product produced by mechanical separation should be labeled as ''mechanically separated (chicken, turkey, or other kind of poultry) with skin,'' because consumers have a ''right-to-know'' that skin and other ''by-products'' are present. Two stated that MSP should be listed in the ingredients statement on a product's label. Other commenters also suggested that there should be full disclosure of all ''ingredients'' resulting from the mechanical deboning process, including bone particles, marrow, kidneys, sex glands and lungs. Another commenter disagreed with the Agency's proposed requirement to label MSP from fowl as such.

In response to comments that stated that MSP should be labeled to reflect the presence of skin, skin is a naturally existing edible component of poultry. Consumers have historically accepted and purchased whole poultry carcasses (e.g., ''basted young turkey'') and parts of carcasses (e.g., ''chicken drumsticks'') with skin, as well as cooked poultry products, e.g., fried chicken, without the presence of skin being specifically reflected on the product's label. FSIS believes that the presence of skin should be labeled only when it is present in excess of natural proportions because this would be a condition in conflict with what a consumer expects poultry to be. If skin is added to a product and

[9] This report is available for public review in the FSIS Docket Clerk's office.

is present in an amount that exceeds that found naturally on the carcass or the part of a carcass according to the figures presented in the regulations (9 CFR 381.117(d)), the label must reflect the presence of skin. FSIS has determined that the name of the product (e.g., ''Mechanically Separated (Kind of Poultry) (MSP))'' must be followed immediately by the phrase ''with excess skin'' unless it is made from poultry product that does not include skin in excess of the natural proportion present on the whole carcass, as presented in the regulations.

Furthermore, there must be appropriate descriptive terminology on the labeling of MSP (with or without skin in excess of natural proportions) if heat treatment has been used in the preparation of such product, e.g., ''cooked mechanically separated (kind of poultry).'' Because cooking would affect the use of MSP, FSIS is requiring that such characteristic be clearly identified on the label when MSP leaves the establishment at which it is manufactured. The poultry products inspection regulations already require that information on use, including deviations from the natural whole carcass proportion of skin as well as the fact of cooking, appear on the label of boneless poultry products produced by mechanical separation (9 CFR 381.117 (d)). The presence of skin or its presence in excess of the natural whole carcass proportion would continue to affect product use if the regulations are amended. The use of heat treatment in the preparation of the product also would be of continuing relevance (9 CFR 381.157(a)). FSIS is requiring the labeling for excess skin in MSP and for heat treatment of MSP in order to assure consistency with regulatory requirements in 9 CFR 381.117 (d) for boneless poultry products and, thereby, to prevent the adulteration and misbranding of finished poultry products and meat food products.

In response to other comments on the need for disclosure of the potential constituents of the starting materials from which MSP results (i.e., bones with muscle tissue and other edible tissue, with or without skin), FSIS has certain regulatory requirements in this final rule or currently in the regulations that address bone particles, kidneys, sex glands, and lungs that negate the need for specific labeling of these constituents.

This final rule will continue the current limit of 1 percent bone solids (measured as calcium) that has been applied to all boneless poultry products since 1969. The size of bone particles has been limited by this final rule as a process control criterion to ensure that the process of mechanical separation is operating in accord with good manufacturing practices. There are no health or safety issues concerning the bone content or bone particle size criteria being established by this rule. Furthermore, the requirement that processed poultry (and meat food) products bear nutrition labeling that includes a calcium declaration in the Nutrition Facts panel will provide meaningful information to consumers who wish to monitor their calcium intake and will reflect the calcium contributed to a product from bone. For these reasons, specific labeling that addresses the presence of bone and bone particles is not necessary.

In regard to the comments on the need to label the presence of bone marrow, no factual basis was provided that would justify such labeling. As explained below, the Agency believes such labeling is unnecessary due to the extremely small amount of marrow that is potentially present, the composition of marrow, the lack of any health or safety concerns about bone marrow from poultry bones, and the role of nutritional labeling in disclosing any potential nutritional impact from the presence of bone marrow in a product. Discussions with poultry scientists, physiologists and geneticists at a variety of universities and research organizations support this conclusion. Based on the limited available data and the discussions with these experts, the following response to the comments on the need for labeling bone marrow in MSP is offered.

Most of the ready-to-cook poultry marketed today are raw, uncooked young poultry carcasses. The bones with attached edible tissue of this class of poultry represent the bulk of the starting materials from which MSP is produced. Young chickens, i.e., broilers, are typically less than 7 weeks of age (although the poultry products inspection regulations, 9 CFR 381.170, define them as being under 13 weeks). Young turkeys are typically less than 8 months of age according to the poultry products inspection regulations (9 CFR 381.170). The young age at which these birds are marketed does not provide time for the production of substantial bone content and, thus, bones from such poultry would not contain much marrow. Moreover, the physiology of poultry is such that, in order for the birds to fly, their bones cannot be dense with tissue and most of the bones could be categorized as being composed mostly of air with minimal tissue (marrow) content. In fact, references [10] indicate that the bones of most birds are porous; many are filled with air, not marrow, and are connected to the respiratory organs. The bones with some marrow are mostly the larger ones, e.g., the leg bones, and are involved in blood production, the function of ''marrow.'' In actuality, the bone marrow represents part of the bird's vascular system.

Information on the actual amount of marrow in poultry bones is lacking. According to the 1979 report entitled ''Health and Safety Aspects of the Use of Mechanically Deboned Poultry,'' marrow content varies in amount with age of the bird, and varies between different bones from the same bird. Determining the actual amount of marrow is difficult because it is difficult to separate marrow from the inner surfaces of bones, and to determine what proportion of the separated tissue is actually ''marrow.'' Moreover, because bone marrow is composed of fat, heme pigments, blood cells, and other constituents normally found in the edible tissue of poultry, it would be difficult to distinguish it from the other edible tissue comprising MSP to determine the minimal amount that may actually be contributed to MSP.

However, with regard to the minimal contribution of bone marrow to MSP that may be possible, it has not been reported to be a health or safety concern. The 1979 Report, the most comprehensive review of MSP to-date, is reliable today as an information source because the basic composition of poultry that would be the starting materials for MSP has not changed since the report was prepared. The 1979 Report made no recommendations regarding the presence of marrow and the need for specifically labeling bone marrow.

Therefore, because it has been estimated that there would be an extremely small marrow constituent in MSP, so small and so similar in composition to other components of MSP that it would be difficult to quantify it, and that there are no known health or safety issues with regard to bone marrow, there is no basis for the specific labeling of bone marrow in MSP. If data on the quantity of bone marrow in MSP become available at some point in the future that would present a basis to reconsider this position, the Agency would certainly reconsider it.

[10] Terres, J.K., 1991. The Audubon Society Encyclopedia of North American Birds, Wings Books, New York. A copy of this reference is available for review in the FSIS Docket Clerk's office.

The 1979 Report did, however, suggest that bone marrow is a potential source of cholesterol in MSP, in addition to that contributed by skin and muscle tissue. The 1979 Report recommended that because of the potential contribution of cholesterol in MSP to foods, which may be of importance to people who have the hereditary condition known as hypercholesterolemia, it is desirable to identify products that contain MSP. This final rule requires that the MSP in a product be labeled and, thus, the recommendation of the 1979 Report has been accepted. More importantly, recent regulations on nutrition labeling address the issue of the potential contribution of cholesterol to the diet from any food. Thus, the potential minimal contribution of marrow to the cholesterol content of a product would be reflected in the mandatory labeling of cholesterol, which is reflected in the Nutrition Facts panel of a product's labeling.

As noted, raw, uncooked young poultry carcasses make up the majority of the ready-to-cook poultry marketed today. Young poultry carcasses are currently sold with kidneys and have been historically sold in this manner. The presence of kidneys in young poultry does not pose a health or safety concern because there are no constituents, e.g., heavy metals, known to be present in these kidneys that are of potential concern. Kidneys from young poultry can be present in the poultry purchased at the supermarket and in the poultry products consumed at retail fast food outlets.

FSIS does, however, require the removal of kidneys of mature turkeys and chickens from their carcasses before completion of the eviscerating operations during the slaughtering process (9 CFR 381.65(d)). Kidneys of mature poultry pose a potential health concern because of the possibility of the presence of certain constituents in these organs, e.g., heavy metals, such as cadmium, which are deposited in the kidneys of older birds over time.

Since kidneys of young poultry pose no health or safety concern and have been historically accepted in ready-to-cook poultry, there is no basis to require specific labeling of these on a product's label. Furthermore, since kidneys from mature poultry must be removed, there is no basis for requiring labeling of kidneys from mature poultry.

In response to comments on the presence of sex glands in MSP, mature reproductive organs (or sex glands) are precluded from being present in ready-to-cook poultry, i.e., poultry subsequent to the slaughtering process, by the poultry products inspection regulations (9 CFR 381.1(b)(44)). Therefore, mature sex glands cannot be present as part of the carcasses or parts of carcasses that are the starting materials from which MSP is made. Mature male sex glands are, however, marketed as an edible poultry product known as ''chicken or turkey fries'' in various regions of the United States.

There are no prohibitions on the presence of immature sex glands, however, in poultry carcasses or parts of carcasses sold to the consumer, or in ready-to-cook poultry used as starting materials for MSP. Immature sex glands have historically been present in these products because they are considered to be an indistinguishable part of the edible tissue of poultry. The young age at which most chickens and turkeys are marketed (as previously noted) does not provide ample time for the development of reproductive organs, e.g., in chickens, sexual maturity of the testes and ova does not begin until about 20 weeks of age. At 6 or 7 weeks of age, the age at which most broilers (the source of most starting materials for MSP) are marketed, the sex glands are merely a thin membrane covering over undefined tissue which is no different in biological or chemical function than other, edible tissue of the carcass. At 6 or 7 weeks, the weight of the barely distinguishable, inert tissue that will later become the sex glands has been estimated to be less than a tenth of a percent of the weight of the raw, uncooked broiler. There are no health or safety concerns related to immature sex glands. Thus, because the tissue of immature sex glands is virtually indistinguishable from other edible poultry tissue and there are no health or safety concerns related to immature sex glands, there is no need to require specific labeling of their presence in a product.

With regard to poultry lungs, poultry lungs must be removed during the processing of ready-to-cook poultry. Lungs are not defined as part of the edible portion of ready-to-cook poultry and must be removed according to the poultry products inspection regulations (9 CFR 381.1(b)(44)). Therefore, specific labeling regarding the presence of lungs is not needed, since lungs are removed before the starting materials used for MSP are obtained.

As noted, a comment was received on the need for the proposed labeling requirement for MSP made from fowl. Because FSIS is not restricting the use of MSP made from fowl, it is eliminating the proposed labeling requirement which requires products made with mechanically separated chicken from fowl to contain on the label the phrase ''made from fowl'' after the product name (e.g., ''mechanically separated chicken (made from fowl)).''

D. Nutrition

Although FSIS did not propose any specific requirements that addressed nutrition, the Agency did receive several comments related to ''Nutrition Facts'' and cholesterol. Fifteen commenters stated that the ''Nutrition Facts'' on product labels is a reflection of the product formula that will satisfy consumers concerning poultry product produced by mechanical separation. Three other commenters stated that cholesterol is not an issue in poultry product produced by mechanical separation.

FSIS recognizes that a recommendation in the 1979 Report was to label products containing MSP with cholesterol content information. This recommendation was based on the evaluation of cholesterol contents of different MSP products that showed they were nearly double the contents in hand-deboned poultry. However, it was stated that, based on consumption estimates, daily increases in cholesterol consumption from use of MSP would be negligible on a per capita basis, and would not pose a health hazard for the general public. It was noted that, for a small segment of the population which must limit their intake of cholesterol for health reasons, foods containing MSP should be specifically labeled to show its presence. However, specifically labeling cholesterol on products containing MSP is not an issue because the provisions of the nutrition labeling regulations (58 FR 632) published by FSIS, which were effective July 6, 1994, would be a means of educating consumers regarding certain nutrients and other components of processed meat and poultry products produced by mechanical deboning, including cholesterol.

E. Safety Concern Regarding Poultry Products Produced by Mechanical Separation

FSIS received 1426 comments regarding the safety of poultry product produced by mechanical separation. Fourteen hundred and twenty commenters stated that there are no safety concerns regarding the use of poultry product produced by mechanical separation. Some of the commenters stated that there are no bone particles of a size that would pose a health concern. Five of the commenters believe that Hazard Analysis and Critical Control Point (HACCP) addresses the needs for process controls that would be related to

poultry product produced by mechanical separation. One commenter suggested that the proposed rule has no conceivable relationship with health or safety, and is a timely example of unnecessary regulation.

In addition, one commenter stated that there are microbiological concerns specific to poultry product produced by mechanical separation. The commenter pointed out that the skin of poultry, including pin feathers, feather particles, and hair are sources of potential microbiological contamination.

FSIS agrees with the commenters that there are no unique safety or health concerns regarding the use of poultry products produced by mechanical separation. Although the data reviewed in the 1979 Report indicate that poultry products produced by mechanical separation generally are acceptable from a microbiological standpoint, the data also show that, where bacterial loads tend to be higher, it can be attributed to the starting material used. This is not unique to poultry products produced by mechanical separation; it can be applied to other finely comminuted and comminuted products as well. FSIS is currently developing a separate rulemaking on HACCP and pathogen reduction efforts that will deal with this issue more fully for all poultry and meat products, including poultry products produced by mechanical separation, and the material from which they are manufactured.

F. Economic and Market Impact

FSIS received 1720 comments on the economic and market impact of the proposed rule on industry. The comments fell into four general categories: (1) The Agency's economic analysis was not sufficient; (2) the new labeling requirement would reduce the demand for products containing MSP; (3) the labeling costs are underestimated; and, (4) the meat industry has been hurt by a similar labeling requirement. These comments are presented and responded to below.

Adequacy of the Agency's Analysis on Economic Impacts

The Small Business Administration (SBA), citing many of the industry objections to the proposed rule, advises that it does not concur in the Administrator's conclusion that the proposed rule will not have a ''significant economic impact on a substantial number of small entities,'' and that, therefore, under the Regulatory Flexibility Act, a more substantial economic analysis is required to support continued rulemaking in this matter. SBA states its belief that further analysis would reveal significant additional costs to industry and disproportionate impacts on small entities, and would disclose other, less burdensome regulatory options.

Others made comments similar to those of the SBA, namely, that the economic analysis of the proposed rule was inadequate and that the proposal constitutes a major rule requiring a far more detailed economic analysis prior to final rulemaking.

Neither the SBA comment nor any other comment received provides data or other evidence that would cause the Agency to alter its estimate of the impacts outlined in the proposal or the economic assumptions upon which they are based. No new evidence has been provided that suggests that this rule will have a disproportionate, or even a significant, economic impact on a substantial number of small entities. Moreover, FSIS believes that the 12-month period prior to implementation of the final rule and its requirements, including the labeling requirements, will render the attendant costs to manufacturers, including small businesses, negligible.

Proposed Requirement Would Reduce Demand for Product

Several commenters believe that the effect of the labeling requirements will be a significant economic and market impact on manufacturers of MSP and that the impact has not been adequately considered by the Agency. It is their belief that this impact would come from the fact that the new label would be unappealing to consumers and would lead commenters to believe that the product is inferior to what they are used to buying, or that something new has been added to the product, or that the product has undergone other changes. This confusion would, they believe, adversely affect demand for products containing MSP.

One commenter indicated that many manufacturers may choose to avoid the misleading connotations of the proposed labeling and reformulate their products with other, more costly ingredients. The commenter further stated that if only 25 percent of the usage of this ingredient were curtailed on this basis, net costs to consumers from such manufacturing decisions would exceed $134 million dollars per year.

Another commenter provided the information that the current market price quotes for raw comminuted turkey meat (frozen, 20% skin) are less than current price quotes for hand-deboned breast and scapula trim meat and boneless, skinless thighs by about $0.50/lb. to $1.00/lb., in order to illustrate that reduced purchases due to the proposed labeling would force industry to use higher cost ingredients such as hand-deboned and boneless meats and that such costs would be directly passed on to the consumer.

Another commenter raised the same issue, indicating that companies that are apprehensive about the labeling change and that fear that their brands will be damaged by the potential negative connotation will reformulate products with higher cost materials. According to this commenter, reformulation will have the effect of increasing the cost of raw materials for both poultry and red meat, ultimately raising the consumer's cost to purchase these products. The commenter stated that the proposal did not address the cost of replacement raw materials and the effect on the raw materials market and believes that if these factors were included in the economic impact, the cost would be between $150 and $200 million.

FSIS has not acquired any reliable data to support the assertion that this rule's labeling requirements will adversely affect the demand for products containing MSP. FSIS believes, however, that if the rule's labeling requirements do reduce demand to some extent for the product or products containing MSP, then it is difficult to draw any conclusion other than that the consumer has been misled by the absence of such labeling.

The primary objective of the Agency's labeling authority is to facilitate informed purchasing decisions. If, as a result of labeling requirements, some consumers will not want the products such evidence would strongly suggest that such labeling is needed. It is the responsibility of FSIS to help ensure that labeling is not deceptive or misleading, and it would be contrary to the Agency's statutory objectives to permit misleading labeling.

The Agency does not believe, however, that it is likely that consumers will face less choice in the market and be forced to buy similar products with higher-cost ingredients because of this rule. In an industry as competitive as the poultry industry, the products demanded by the consumer will be produced. Price is an important factor in selling products, and consumers are unlikely to abandon a popularly-priced, high-quality product which they have found to be satisfactory simply because it has a more informative label. Further, if some consumers shift to their purchases to higher-priced products, it is difficult to see why this would not be a favorable outcome for both the consumer and the industry. The Agency

believes that the poultry industry is a mature and sophisticated industry that is capable of producing and marketing any array of products for which there is a demand, and that this rule will not restrict or hamper the industry's ability to meet the needs and desires of its customers.

The Red Meat Experience With Similar Labeling

One commenter stated that the meat industry's experience in a comparable regulatory situation strongly, if not conclusively, suggests that assumptions made in the economic analysis are invalid.

The Agency assumes this commenter is referring to the widely held belief that product labeled as ''Mechanically Separated (Species),'' here referred to as MSM, has not been a highly profitable undertaking for the red meat industry. The Agency has no data to confirm or refute this proposition. It does believe, however, that the red meat and the poultry situations are not comparable from an economic point of view.

The red meat industry never had an established market for MSM, and it would be difficult to attribute the asserted lack of success to the required label rather than to the decision not to try and build that market. Further, it is not obvious that the MSM label is solely responsible for the decision not to try to build the market. Numerous other factors, particularly the marketing expense of launching new products with an unknown demand, could have been a determining factor in the decision not to try to build a new market for MSM products.

The poultry industry, on the other hand, has established markets and satisfied consumers for products that have always been made with MSP. Its position is, therefore, not comparable to that of the red meat industry which would have to take a chance on new products with an unknown consumer reception.

Labeling Costs

One commenter stated that his company would have more than 250 labels affected by this rule. The company believes that it will cost a minimum of $1,000 for each label change, which includes internal management time, printing costs, and obsolete label inventory.

The cost of labeling changes can be significantly reduced by allowing companies to use up their old stocks, which the rule has provided for by making the rule not effective until one year from its publication date.

G. Finished Poultry Products and Meat Food Products

Several commenters disagreed with the Agency's proposed position to regulate MSP as a distinctive ingredient with standardized characteristics that is defined by its own name, e.g., ''Mechanically Separated (Kind of Poultry)'' which must be declared in the ingredients statement of finished product labels. One commenter noted that the Agency has provided no evidence of salient differences between what they refer to as ''finely ground poultry'' and hand-deboned poultry to suggest that mechanically separated poultry should be regulated as proposed. The commenter further stated that the Agency has provided no legitimate reasons for treating mechanically separated poultry and MSM similarly and for regulating the final products based on the process used to make them. The commenter noted that the poultry industry uses raw materials containing greater proportions of meat and produces a product much lower in bone content, which is analytically similar to whole muscle cuts from the same species.

In addition, another commenter suggested that since calcium and cholesterol nutrition information is fully disclosed in the Nutrition Facts panel, which is a reflection of the product formula, the term ''mechanically separated'' is not needed in the ingredients statement.

FSIS believes that such a labeling requirement is necessary to fulfill its statutory responsibility to protect consumers by assuring that the labels of finished poultry products and meat food products are accurate. MSP is materially different in form and texture as compared to hand-deboned poultry, and this is a direct result of the mechanical separation process and the types of starting materials used to make MSP. MSM is a similar red meat product, resulting from a similar process. FSIS has concluded that MSP should be defined by its own name, i.e., ''Mechanically Separated (Kind of Poultry),'' and should be declared in the ingredients statements on finished product labels.

The starting materials used to make MSP may vary in the amount of edible tissue remaining on the poultry bones after hand-deboning, but the variance is minimal because a substantial portion of the muscle and other edible tissues has already been removed by hand-deboning methods. That a significant amount of muscle remains on the bones is not likely because the process of mechanical separation for both poultry and livestock has been designed to salvage the tissue left on the bones to produce a wholesome, low-cost, and functional poultry product. The comparison made by a commenter regarding the amount of tissue on starting materials for making MSP and materials used to make MSM is irrelevant. It is the fact that the process starts with bones on which a minimal amount of tissue remains and that both processes are designed to salvage muscle and other edible tissues, and both processes result in a paste-like and batter-like product in terms of form and consistency, that warrant their distinct declaration.

H. Ergonomic Impact

FSIS received several comments regarding the ergonomic impact of this rule. According to the commenters, mechanical deboning systems have substantially lowered the risk of cumulative trauma disorders (CTD) resulting from repetitive hand, arm, and wrist motions. However, the commenters indicated that industry may be forced to use more hand-deboned products in lieu of this wholesome mechanically separated product due to this rule. The commenters believe the rule negatively impacts the industry's ability to use mechanical deboning and other ''mechanical'' means in harvesting meat from turkey and chicken parts and carcasses. They indicated this is because the labeling requirements will diminish sales and production of products containing MSP and make the industry revert to using hand-deboned poultry.

FSIS agrees that it is likely that mechanical separation systems have substantially lowered the risk of cumulative trauma disorders, although there were no data supplied to document this conclusion. However, FSIS does not agree with the assertion that this rule will force industry to use more hand-deboned products, in lieu of mechanically separated product, because of the requirement that use of MSP in a product be separately reflected in a product's ingredients statement. This assertion appears to be based on the assumption that it would be economically feasible to hand debone the materials from which MSP is made. However, FSIS does not believe that it would be economically feasible for the industry to hand debone, as opposed to mechanically separate, the bits and pieces of poultry that remain on poultry carcasses, and parts of carcasses from which mechanically separated product is obtained.

I. Miscellaneous

FSIS received other miscellaneous comments which addressed the following issues: (1) use of MSP in the manufacture of a flavoring should not require a separate and distinct listing of MSP as an ingredient of the flavoring in the ingredients statement of the product in which it is used, (2) an extension of the comment period for 30 days should be granted, and (3) industry should be given sufficient time to use up most of its printed labels before the final rule's new labeling requirements become effective.

FSIS is familiar with the issue raised by the commenters that MSP is frequently used as a protein source for ''reaction'' (or process) flavors produced under the jurisdiction of the Food and Drug Administration (FDA) and may currently be labeled as ''(kind) flavor'' according to the guidelines on reaction flavors established by the Agency. FSIS does not intend to change these policies because the chemical reactions involved in manufacturing process flavors involves the removal of the soluble flavoring components of the poultry ingredients and does not include the solid portion of the poultry ingredients.

At the request of commenters, FSIS extended the comment period for the proposed rule an additional 30 days to March 6, 1995. FSIS considered these requests to have additional time to study and develop information relating to the proposal to be reasonable. Also, as discussed previously, FSIS has made its final rule effective one year from its date of publication, which should allow ample time to use up label stocks.

Executive Order 12866

This final rule has been determined to be significant and has been reviewed by the Office of Management and Budget under Executive Order 12866.

Total federally inspected broiler and turkey meat production in the United States in 1993 was about 27 billion pounds on a ready-to-cook basis (i.e., subsequent to the slaughtering step in processing). (Broilers represent the majority of chickens grown and slaughtered in the U.S.) Broiler production was 22.2 billion pounds and turkey 4.8 billion pounds. Continued growth in poultry production has resulted in large increases in the volume of poultry meat going into further processed products such as bologna, hot dogs, fritters, patties, and luncheon meats, many of which use MSP. FSIS has estimated that 1 billion pounds of poultry product is processed annually into MSP, with a yield of 70%, or 700 million pounds of MSP product for human use. (Industry sources suggest that a larger amount of MSP product is produced annually.) FSIS estimated that 400 million pounds are used in sausage products and 300 million pounds in patties and nuggets. In any case, size of the market does not directly affect the cost of this rule (see below).

The Broiler Council estimates that broiler meat is produced in about 200 establishments, of which 50 are further processing establishments. MSP is produced in about 108 establishments. About 25–30 of these establishments with MSP equipment produce hot dogs. The product from the other 75–80 establishments is sold to establishments that further process poultry or to red meat processors. Industry sources indicate that some small firms specialize in MSP production, buying carcasses from poultry slaughter establishments for further processing.

Based on inspection task records, FSIS estimated that 108 establishments produce (or are capable of producing) MSP. An assessment of MSP production by establishment size is not available. However, total further processed product production by size of establishments shows 7 establishments with production less than 10,000 pounds of MSP annually. The average production of the 108 establishments is 51 million pounds of all further processed products.

Under this rule, products containing mechanically separated poultry are required to separately label ''Mechanically Separated (Kind of Poultry)'' in the list of ingredients. There is no precise information on the total number of products that currently contain MSP because MSP may appear simply as ''chicken'' or ''turkey'' in product formulations in which it is an ingredient. However, an estimate of the number of products containing MSP can be made by estimating the number of labels for MSP and for categories of products to which it is frequently added. These estimates were made by using the database of label information that is maintained by FSIS' Food Labeling Division, as part of the Agency's prior label approval system. There are 602,000 approved labels for poultry and meat, not all of which are necessarily in use. These include 529 labels for MSP itself. There is also an unknown number of labels for products containing MSP, such as frankfurters, chili, bologna, poultry baby foods, chicken nuggets or patties. FSIS estimates that, in total, about 5,000 products would require relabeling. There is no currently available data on the size breakdown of the establishments producing products containing MSP.

Costs and Benefits of the Rule

Analysis of the economic impact of a rule requires consideration of all significant costs and benefits.

Benefits

The benefits are the values consumers place on the ability to make a more informed purchase based on more accurate labeling. Informed purchases, which in this case result from accurate labeling, are an essential principle of the free market in which meat and poultry products trade and one of the principal justifications for the regulation of labels. FSIS has a statutory mandate to avoid false and misleading labeling. Therefore, if, as the Agency has determined here, a label is misleading or false, the Agency has a responsibility to correct that situation.

As discussed earlier in the preamble to this rule, several commenters suggested that the labeling requirements of the rule would adversely affect demand for products made with MSP. FSIS has not acquired any data that can be used to estimate the impact this rule will have on the demand for MSP. However, the Agency's experience is that consumers do distinguish between muscle meat and more finely comminuted product. It is also apparent that there are texture differences in these two types of products. The public comments on this action have reinforced this belief. Many commenters have stated that they believe consumers will not buy the product if it is labeled under the new requirement. Further, the producers of a similar red meat product, which already requires labeling of the type promulgated by this rule, claim that the required labeling keeps the public from buying their product. The Agency has not quantified the magnitude of change in consumer demand under the present rule, but it does recognize that these comments demonstrate there is widespread recognition that comminuted product could be viewed less favorably than muscle meat by the consumer.

Furthermore, as also discussed earlier in the preamble to this rule, the Agency has concluded that use of the term ''mechanically separated'' truthfully describes the nature of the product and that purchases of MSP using this label will accurately reflect the real value placed on it by consumers.

As a result of the current labeling practices, consumers are being misled and are possibly consuming more MSP than they otherwise would if they had better information. The extent to which

consumers reduce their demand for this product as a result of the labeling change will reflect the level to which consumers have been misled. The increased value placed by consumers on inaccurately labeled MSP products represents a welfare loss to consumers and society. The misdirected purchasing power placed on inaccurately labeled MSP products could be used to purchase other products of higher value to consumers. The greater the change value placed on this product by consumers, the greater the benefits of the rule. Revenue losses producers experience due to this shift in consumer demand are not social welfare losses, but instead represent resources misallocated toward the excess production of products containing MSP. To the extent that market prices for products containing MSP decline in response to shifts in consumer demand, losses experienced by producers represent gains to consumers and, thus, are in fact transfer payments from producers to consumers.

Taking into account consumer experience with MSP leads the Agency to believe that any change in consumer behavior will be negligible, and FSIS has not acquired any data to show any negative impact on poultry or poultry products made with MSP. The Agency also believes that MSP should continue to be a wholesome and safe low-cost source of protein with nutritional attributes comparable to ''chicken'' or ''turkey.'' As discussed earlier, MSP has certain desirable attributes that will ensure its continued use as an ingredient in many products.

Costs

The Agency recognizes that it has a responsibility to keep the cost impact of this rule to a minimum to keep the burden of regulation as low as possible on the industry. It has done this by giving sufficient time for most businesses to use up their inventory of labels, thus substantially reducing the cost associated with the rule.

Possible sources of costs associated with the rule include the following items:

A. Labeling Changes and Inventory

Under the final rule, finished products containing mechanically separated poultry are required to have ingredient statement labeling of the mechanically separated poultry as ''Mechanically Separated (Kind of Poultry).'' As reported in the proposed rule, estimates range from $200 to $3,000 per product for a simple product ingredient statement label change depending on the type of label. Comments in response to the March 1994 ANPR indicate that changes to the ingredients statement of most labels to which the final rule will apply would fall in the lower end of this range (about $600). FSIS previously reported in the proposal that, assuming an average cost of $1,000 per product, the cost of relabeling would be $5 million ($1,000 times 5,000 products). These estimated costs that were reported in the proposed rule assumed a typical 30-day effective date for implementation of the final rule and its requirements.

However, by establishing the one-year period from publication to the effective date for implementation of the final rule, labeling costs would be substantially reduced. The cost of relabeling would be negligible because the mandated MSP label changes can be coordinated with other label changes planned or required during the year-long period prior to the effective date of the MSP rule. Many firms routinely make label changes for existing products. For example, about 50% of the 180,000 labels submitted to FSIS each year for approval are for label changes on existing products. These label changes are made for various reasons that reflect the kinetic nature of the food industry and, in particular, the fast-paced research and development of new and modified meat and poultry products, e.g., changes to incorporate less costly, new, or more effective ingredients that extend shelf-life, improve taste or texture, or replace fat; changes to add recipes or consumer purchase incentives to labeling; changes to make new or different claims about a product's nutrient content or performance; changes to alter features such as net weight or logos; or changes to modify the color or size of print. These new MSP labeling requirements, therefore, can be worked in with other routine label changes. The modest costs associated with the MSP labeling change are nonetheless necessary to assure that consumers receive meat and poultry products with informative and nonmisleading ingredients statements.

Some firms may discard non-compliant labels when the final rule goes into effect. A survey of meat and poultry companies for the nutritional labeling rule indicated that firms carry an average label inventory of 5 to 6 months. Knowing this, FSIS established a 12-month period to allow ample time for an orderly transition to the new requirements of the rule, including the labeling requirements, and to assure that manufacturers of MSP, and of poultry and meat food products in which MSP is used as an ingredient, have ample time to exhaust current label stock. Therefore, it is not anticipated that manufacturers will have to dispose of label inventories that were printed or ordered for printing prior to publication of the rule. Thus, with the 12-month compliance period, inventory losses, if any, would be minor.

B. Bone Particle Size

A new requirement limits maximum bone particle size. FSIS believes bone particle size will not have a significant effect on actual production and is a measure that augments the current requirement of one percent or less bone solids to show that the process of separating bone from meat is operating effectively. As previously stated, FSIS did not in its proposal, nor is it in this final rule, requirement testing or sampling for bone particle size in MSP. The Agency has concluded that manufacturers should have the flexibility to decide how best to assure compliance with the bone particle size requirement.

Furthermore, the Agency agreed with commenters, as stated previously, that the requirements for keeping records on bone particle size (and bone solids) should not be mandated and, in this respect, will permit flexibility in meeting the rule's requirements. Thus, additional potential costs have been eliminated.

C. Other Costs

The Agency does not agree with the view presented by many commenters that any reduction in income from the reduction of consumption of MSP product labeled under the new requirement should be considered a cost of this rule. To the extent that purchasers reduce their consumption of MSP products because of the new labeling, the revenue received by the industry from such purchases is really revenue derived rom an inaccurate and misleading label, and are not properly considered as costs attributable to this rule given the statutory mandate.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing with respect to the premises, facilities, and operations of federally inspected establishments any requirements that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, impose recordkeeping and other requirements within the scope of section 202 of the

FMIA and section 11 of the PPIA, if consistent therewith, with respect to any such federally inspected establishment. States and local jurisdictions are also preempted under the FMIA and the PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA and PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements that are at least equal to those required under the FMIA and PPIA. The States may, however, impose more stringent requirements on such State inspected products and establishments.

No retroactive effect will be given to this final rule. The administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge to the provisions of this final rule, if the challenge involves any decision of a program official. The administrative procedures specified in 9 CFR parts 335 and 381, subpart W, must be exhausted prior to any judicial challenge to the application of the provisions of this rule with respect to labeling decisions.

Effect on Small Entities

The Administrator has determined that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). Because the implementation date for this final rule provides ample time for transition to the new requirements, including the labeling requirements, producers with smaller lot size than large producers will not have higher compliance costs per pound of product because of relabeling costs attributable to the rule. By establishing the one-year effective date for implementation of the final rule, new labeling costs will be substantially reduced. The cost of relabeling would be negligible because the mandated MSP label changes can be coordinated with other label changes planned or required during the year-long period prior to the effective date and implementation of this rule.

Paperwork Requirements

This final rule will allow establishments to voluntarily maintain records of bone solids content and bone particle size as a measure of process control. FSIS will allow manufacturers flexibility to determine the best methods for compliance with these requirements, provided such procedures and methods are in accord with good manufacturing practices.

This final rule will also require labels of poultry products produced by mechanical separation (i.e., products currently termed mechanically deboned poultry or MDP) or products containing this ingredient to be revised to include in the ingredients statements the term ''Mechanically Separated (Kind of Poultry)'' and be submitted to FSIS for approval. However, by providing a one-year period between publication of this rule and the effective date for implementation, labeling costs will be substantially reduced. The cost of relabeling would be negligible because the mandated MSP label changes can be coordinated with other label changes planned or required to meet other regulatory tenets during the year-long period of promulgation of the MSP rule and its enforcement.

The paperwork requirements contained in this final rule have been approved by the Office of Management and Budget under control number 0583–0101.

List of Subjects

9 CFR Part 318

Meat inspection.

9 CFR Part 319

Meat inspection, Standards of identity

9 CFR Part 381

Food labeling, Poultry and poultry products, Standards of identity.

Final Rule

For the reasons set forth in the preamble, FSIS is amending 9 CFR parts 318, 319, and 381 of the Federal meat and poultry inspection regulations as follows:

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS: REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 318.6 is amended by adding a new paragraph (b)(13) to read as follows:

§ 318.6 Requirements concerning ingredients and other articles used in preparation of products.

* * * * *

(b) * * *

(13) Use of ''Mechanically Separated (Kind of Poultry),'' as defined in § 381.173 of this chapter, in the preparation of meat food products shall accord with § 381.174 and all other applicable provisions of this subchapter.

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

3. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

4. Section 319.180 is amended by revising the sixth sentence of paragraph (a) and the seventh sentence of paragraph (b).

§ 319.180 Frankfurter, frank, furter, hot dog, weiner, vienna, bologna, garlic bologna, knockwurst, and similar products.

(a) * * *. Such products may contain raw or cooked poultry meat and/or Mechanically Separated (Kind of Poultry) without skin and without kidneys and sex glands used in accordance with § 381.174, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and Mechanically Separated (Species) used in accordance with § 319.6. * * *

(b) * * *. These sausage products may contain poultry products and/or Mechanically Separated (Kind of Poultry) used in accordance with § 381.174, individually or in combination, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and may contain Mechanically Separated (Species) used in accordance with § 319.6. * * *.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138F; 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.17, 2.55.

4. Section 381.15 is amended by revising paragraphs (a)(1), (a)(2), (b)(2), and (c)(1) to read as follows:

§ 381.15 Exemption from definition of ''poultry product'' of certain human food products containing poultry.

* * * * *

(a) * * *

(1) It contains less than 2 percent cooked poultry meat (deboned white or dark poultry meat, or both) and/or

''Mechanically Separated (Kind of Poultry)'' as defined in § 381.173;

(2) It contains less than 10 percent of cooked poultry skins, giblets, or fat, separately, and less than 10 percent of cooked poultry skins, giblets, fat, and meat (as meat is limited in paragraph (a)(1) of this section) or ''Mechanically Separated (Kind of Poultry)'' as defined in § 381.173, in any combination;

* * * * *

(b) * * *

(2) It contains less than 15 percent cooked poultry meat (deboned white or dark poultry meat or both) and/or ''Mechanically Separated (Kind of Poultry) '' as defined in § 381.173, computed on the basis of the moist deboned, cooked poultry meat and/or ''Mechanically Separated (Kind of Poultry)'' in such product; and

(3) * * *

(c) * * *

(1) They contain poultry meat and/or ''Mechanically Separated (Kind of Poultry) '' as defined in § 381.173 or poultry fat only in condimental quantities;

* * * * *

5. Section 381.117 is amended by revising the section title and adding a new paragraph (e) to read as follows:

§ 381.117 Name of product and other labeling.

* * * * *

(e) On the label of any ''Mechanically Separated (Kind of Poultry) '' described in § 381.173, the name of such product shall be followed immediately by the phrase: ''with excess skin'' unless such product is made from poultry product that does not include skin in excess of the natural proportion of skin present on the whole carcass, as specified in paragraph (d) of this section. Appropriate terminology on the label shall indicate if heat treatment has been used in the preparation of the product. The labeling information described in this paragraph shall be identified on the label before the product leaves the establishment at which it is manufactured.

6. Subpart P is amended by adding new §§ 381.173, and 381.174 to read as follows:

§ 381.173 Mechanically Separated (Kind of Poultry) .

(a) ''Mechanically Separated (Kind of Poultry)'' is any product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle and other tissue of poultry carcasses and parts of carcasses that has a paste-like form and consistency, that may or may not contain skin with attached fat and meeting the other provisions of this section. Examples of such product are ''Mechanically Separated Chicken'' and ''Mechanically Separated Turkey.''

(b) ''Mechanically Separated (Kind of Poultry)'' shall not have a bone solids content of more than 1 percent. At least 98 percent of the bone particles present in ''Mechanically Separated (Kind of Poultry) '' shall have a maximum size no greater than 1.5 mm (millimeter) in their greatest dimension and there shall be no bone particles larger than 2.0 mm in their greatest dimension.

(c) ''Mechanically Separated (Kind of Poultry)'' shall not have a calcium content exceeding 0.235 percent when made from mature chickens or from turkeys as defined in § 381.170(a)(l)(vi) and (vii) and (a)(2), respectively, or 0.175 percent when made from other poultry, based on the weight of product that has not been heat treated, as a measure of a bone solids content of not more than 1 percent.

(d) ''Mechanically Separated (Kind of Poultry)'' may be used in the formulation of poultry products in accordance with § 381.174 and meat food products in accordance with subchapter A of this chapter.

(e) Product resulting from the mechanical separation process that fails to meet the bone particle size or calcium content requirements for ''Mechanically Separated (Kind of Poultry)'' shall be used only in producing poultry extractives, including fats, stocks, and broths and labeled as ''Mechanically Separated (Kind of Poultry) for Further Processing.''

§ 381.174 Limitations with respect to use of Mechanically Separated (Kind of Poultry).

(a) A poultry product required to be prepared from a particular kind of poultry (e.g., chicken) shall not contain ''Mechanically Separated (Kind of Poultry)'' described in § 381.173, that is made from any other kind of poultry (e.g., Mechanically Separated Turkey).

(b) ''Mechanically Separated (Kind of Poultry)'' described in § 381.173 may be used in the formulation of any poultry or meat food product, provided such use conforms with any applicable requirements of the definitions and standards of identity or composition in this subchapter or part 319 of this chapter, and provided that it is identified as ''Mechanically Separated (Kind of Poultry).''

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Michael R. Taylor,

Acting Under Secretary for Food Safety.

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