Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 318, and 320

[Docket No. 96–027P]

Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: In 1994, the Food Safety and Inspection Service amended its regulations to recognize that product resulting from advanced meat/bone separation machinery and recovery systems comes within the definition of meat when these recovery systems are operated to ensure that the characteristics and composition of the resulting product are consistent with those of meat. The Agency is proposing to clarify the regulations and to supplement the rules for assuring compliance. In future rulemakings, the Agency expects to apply the process control-performance standards approach of this proposal to other types of operations for manufacturing meat and poultry trimmings.

DATES: Comments must be received June 12, 1998.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 96–027P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250–3700. All comments submitted in response to this proposal will be available for public inspection in the Docket Clerk's office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250–3700; (202) 205–0699.

SUPPLEMENTARY INFORMATION: The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) to protect the health and welfare of consumers by preventing the distribution of meat and meat food products that are unwholesome, adulterated, or misbranded. FSIS's regulations (9 CFR chapter III) distinguish meat (essentially muscle that is skeletal or found in the tongue, diaphragm, heart, or esophagus) from other products of livestock carcasses (§ 301.2). In 1994, FSIS amended its regulations to recognize that product resulting from advanced meat/bone separation machinery and recovery systems comes within the definition of meat when these systems are operated to ensure that the characteristics and composition of the resulting product are consistent with those of meat (59 FR 62551, December 6, 1994).

A livestock (cattle, sheep, swine, goat, horse, mule, or other equine) product is misbranded under any of a number of circumstances, including if its labeling is false or misleading in any particular; if it is offered for sale under the name of another food; if it is an imitation of another food, unless its label bears (in type of uniform size and prominence) the word ''imitation'' and, immediately thereafter, the name of the food imitated; or if it purports to be or is represented as a food for which a definition and standard of identity or composition is prescribed by regulations, unless it conforms to the regulations and its label bears the name of the food specified in the definition and standard (21 U.S.C. 601(n)(1), (n)(2), (n)(3), and (n)(7)). A livestock product is adulterated if any valuable constituent has been in whole or in part omitted or abstracted therefrom; if any substance has been substituted wholly or in part therefor; if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is (economic adulteration) (21 U.S.C. 601(m)(8)). A product that does not come within the definition of meat in § 301.2(rr) may not be marketed as meat, and its use contrary to regulations such as the definition and standard in § 319.15(a) would result in misbranding and economic adulteration.

The FMIA prohibits the preparation of meat or meat food products for commerce except in compliance with the FMIA requirements and the selling, transporting, offering for sale or transportation, or receiving for transportation, in commerce, of meat or meat food products that are capable of use as human food and are adulterated or misbranded (21 U.S.C. 610(a) and (c)). Intrastate operations and transactions are effectively subject to the same prohibitions under State meat inspection programs, which must enforce requirements at least equal to those imposed under the FMIA, or designation for Federal inspection, whereby both intrastate and interstate operations in the State are federally inspected (21 U.S.C. 661(c)(1)).

FSIS now believes that the provisions adopted in 1994 are confusing and need revision to prevent misbranding and economic adulteration. Therefore, the Agency is proposing to clarify the scope of ''bone'' as used in the definition of meat and other aspects of the regulations and to reorganize and supplement the rules for assuring compliance with the regulations, taking into account information and developments since the 1994 rulemaking.

Previous Agency Action

The basis for the 1994 rulemaking was advances in recovery machinery: The development of meat/bone separators that emulated the physical action of hand-held high-speed knives for the removal of skeletal muscle tissue from bone had led to recovery systems that separated meat from bone by shaving, pressing, or scraping the muscle tissue from the bone surface, with the bones emerging essentially intact and in natural physical conformation, resulting in product that is comparable to meat derived by hand deboning (59 FR 62552–53). As FSIS stated in its final rule:

> * * * The machines do not grind, crush, or pulverize bones to separate muscle tissue, and the bones and the interconnecting soft tissues that link bones emerge from the process in a manner consistent with hand-deboning operations that use knives.
>
> * * * The advanced recovery systems produce distinct whole pieces of skeletal muscle tissue with a well-defined particulate size similar in consistency to (species)

trimmings derived by hand-deboning and used to formulate processed meat products. The color * * * is similar to that of (species) trimmings. * * * [T]he meat derived * * * has the functional and chemical characteristics of meat; there are no powdered bone or constituents of bone, *e.g.*, bone marrow, that are not in conformance with the definition and expectation of meat or that would render the product adulterated or misbranded * * * [59 FR 62553–54.]

After monitoring advances in meat/bone separation machinery for a decade, FSIS concluded it should amend its regulations so that they explicitly provided that when skeletal muscle is separated from livestock bones using advanced recovery systems under appropriate controls, the resulting product is treated as meat rather than as mechanically separated livestock product.

Mechanically separated livestock product, unlike meat, is made by mechanically separating and removing most of the bone from attached skeletal muscle of carcasses and parts of carcasses, using machinery that operates on the differing resistance of hard bone and soft tissue to passage through small openings. For 20 years the Department's position has been that although mechanically separated livestock product has many of the characteristics of meat and, as regulated, may be used as a meat ingredient in the formulation of quality meat food products, it is not meat (as defined in § 301.2(rr)). In particular, the consistency of mechanically separated livestock product and its content of bone and certain minerals, as well as muscle tissue, are materially different from those of meat, and these differences have potential consequences for finished product quality and for health and safety (see, *e.g.*, 47 FR 28214, 28223, June 29, 1982). Also, to the extent that it is made from materials which contain spinal cord and bone marrow in addition to muscle and fatty tissue, the cholesterol content of mechanically separated livestock product appears to be greater than the cholesterol content of meat (47 FR 28238).

Part 319 of the regulations specifies ''Mechanically Separated (Species)'' (MS(S)) as the name of mechanically separated livestock product that meets various regulatory requirements and limits the level at which, and products in which, MS(S) may be used (§§ 319.5 and 319.6). The Department has prohibited the use of MS(S) in certain meat food products, based on determinations about the basic characteristics expected in those products, and in baby, junior, and toddler foods, based on a determination that available information was insufficient to conclude that other regulatory restrictions are adequate to prevent the mottling of infants' teeth as a result of increased fluoride intakes (§ 319.6(d); see, *e.g.*, 47 FR 28240–41).

The MS(S) definition and standard does not specify the type of equipment used to separate and remove bone because, as intended by the Department, it covers product manufactured by any machinery that operates on the differing resistance of hard bone and soft tissue to passage through small openings, whether the machinery employs sieves, screens, or other devices and whether or not bones are prebroken before being fed into the equipment. However, the MS(S) definition and standard was not intended to apply to whole pieces of muscle removed from livestock bones by mechanical or other means. (47 FR 28223.)

In 1994, FSIS determined that there were meat/bone separators and recovery systems that were fundamentally different than the machines used to manufacture MS(S). The Agency's final rule specifically contrasted skeletal muscle separated from livestock bones using advanced recovery systems with the characteristics and composition of MS(S). FSIS concluded that, unlike with MS(S), ''consumer expectations of 'meat' are met with regard to the product obtained from the advances in meat/bone separation machinery and recovery systems, because the product's characteristics, in terms of appearance and texture, and its composition are similar to those of 'meat,' as currently defined'' (59 FR 62554).

The amendments adopted in 1994 did *not* change the applicability or requirements of the MS(S) regulations. Instead, they recognized FSIS's conclusion that product resulting from advanced meat/bone separation machinery and recovery systems comes within the definition of meat when the systems are operated to ensure that product characteristics and composition are consistent with those of meat.

In response to compliance concerns raised after the amendments took effect (on January 5, 1995), FSIS surveyed federally inspected establishments known to be using advanced meat/bone separation machinery and a variety of starting materials (in the fall of 1995), met with industry members, and issued a directive to inspection program personnel to increase consistency in the application of regulatory requirements (FSIS Directive 7160.1, September 13, 1996). FSIS then published a notice that summarized the survey results, discussed various issues, and solicited additional data and information from the public (1996 notice) (61 FR 57791, November 8, 1996). The Agency received 34 comments (from regulated industry members, various trade associations, equipment manufacturers, consumer organizations, consultants, academics, an FSIS inspector, and a U.S. Senator),[1] but no new data. The Agency subsequently took steps to assure that, as intended, product which contained spinal cord was not treated as meat (see, *e.g.*, FSIS Directive 7160.2, April 14, 1997).

After considering information obtained since 1994 on production practices and product characteristics, including a 1996 survey of establishments mechanically separating muscle from beef neck bones and additional data subsequently submitted to the Agency,[2] along with the views expressed in the comments submitted in response to the 1996 notice, FSIS came to believe that it is necessary to amend the regulations regarding products resulting from advanced meat/bone separation machinery. FSIS also initiated a review of available information on poultry product processing operations that may present similar issues under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*).[3] However, in view of the concerns about possible incorporation of spinal cord and bone marrow in products resulting from advanced meat/bone separation machinery, the Agency has determined that it should not delay action on this matter. FSIS will consider the poultry product issues during its reevaluation of how FSIS regulates operations for manufacturing meat and poultry trimmings (including grinding, low temperature rendering and other preparation and processing of whole muscle and other starting materials into comminuted livestock and poultry products). The Agency plans to obtain additional information on current industry practices and, in future rulemakings, to apply a consistent

[1] Comments submitted in response to the 1996 notice are available for public inspection in the FSIS Docket Clerk's office.

[2] The ''Advanced Meat Recovery System Survey Project Final Report'' (final report) (prepared February 21, 1997, by Dr. Robert J. Hasiak and Harry Marks), data submitted since the 1994 rulemaking, and an evaluation of information used in developing two of the proposed noncomplying product criteria (''Establishment of calcium and excess iron limits,'' Dr. Daniel L. Engeljohn, FSIS) are available from the FSIS Docket Clerk.

[3] See FSIS's September 20, 1996, letter responding to the National Turkey Federation's request to postpone the effective date of the Mechanically Separated (Kind of Poultry) final rule and adopt a regulation to treat product derived using advanced recovery systems as ''turkey''.

process control-performance standards approach to those operations as well.

Proposed Rule

The Agency's objective for this rulemaking is to assure that the regulations provide clear standards under which industry members assume their responsibility to avoid misbranding and economic adulteration in compliance with enforceable regulatory requirements that include adequate markers for bone-related components at greater than unavoidable defect levels (levels consistent with defects anticipated when meat is separated from bone by hand). In 1994, the Agency expected that the exclusion of meat/bone separation machinery and recovery systems which ''crush, grind, or pulverize bones'' meant that the calcium content limit and the requirement that ''the bones emerge comparable to those resulting from hand-deboning (*i.e.*, essentially intact and in natural physical conformation such that they are recognizable * * *,'' as specified in § 301.2(rr), would be sufficient to ensure that the production process is in control and the characteristics and composition of the resulting product are consistent with those of meat. As discussed below and evidenced by data on product composition that FSIS has evaluated since issuance of the 1994 final rule, FSIS's expectations have not been borne out. FSIS believes that this rulemaking is necessary to accomplish the intended purpose of the amendments adopted in 1994: ensuring control of the production process to prevent the recovery of soft as well as hard bone tissues and providing adequate bases for verifying the exclusion of bone-related components and, thus, the production of meat.

Moreover, the Agency now believes that it is inappropriate to focus on the physical condition of bones, particularly at an intermediate processing step, rather than on the food product being recovered by the machinery. In addition, experience evidences that deciding whether ''* * * bones emerge . . . essentially intact and in natural physical conformation * * *'' calls for such individualized judgments that continuing controversy is inevitable. Application of the emerging bones criterion has involved the Agency and its personnel in questions about bones compressed or compacted during mechanical meat/bone separation into bone ''cakes'' or ''plugs''. Efforts by FSIS personnel to determine by visual examination whether bones—as they emerge or after disassembly—are essentially intact and in the same natural physical conformation as when they entered the system such that they are recognizable as neck bones, rib bones, *etc.* (Paragraphs I.D., E., and F. of FSIS Directive 7160.1) have not resulted in consistent judgments, either during in-plant verifications or in the laboratory.[4]

Nor does the Agency have confidence that these judgments are correlated with the regulatory objective: the operation of recovery systems to prepare products that come within the definition of meat. In FSIS's view, manufacturers should control the advanced recovery production process to prevent the incorporation of soft bone-related components as well as hard bone (bone solids), and the Agency should focus on product composition in verifying whether manufacturers are fulfilling this responsibility.

As is clear from provisions of the proposed rule, however, FSIS views replacement of the essentially intact-natural physical conformation criterion as a question of regulatory focus, not as an abandonment of visual observations. Thus, for example, comparing bones entering and exiting a recovery system may well be appropriate, or even sufficient, when deciding whether spinal cord, a bone-related component, is being incorporated into a product.

During this rulemaking, inspection program personnel will continue to observe conditions that are relevant in determining whether ''recovery systems * * * crush, grind, or pulverize bones'' and, hence, are excluded by § 301.2(rr). However, the Agency intends to withdraw its instruction to inspection program personnel to disassemble bones that emerge in a compacted mass (FSIS Directive 7160.2, Paragraph I.D.2.). Especially when performed before another processing step,[5] this procedure does not appear to be a reliable predictor of whether a system is recovering bone-related components other than calcified tissue as well as skeletal muscle tissue.

Finally, the Agency believes that the structure of the 1994 amendments has contributed to the problem. FSIS's purpose in adding language to the definition of meat in § 301.2(rr) was to clarify—not to expand—the scope of the definition by providing the conditions under which advanced meat/bone separation machinery and recovery systems must operate to yield meat. The Agency now recognizes that addressing these conditions in the definition has resulted in confusion. For example, comments received by the Agency indicate that some members of the public have misconstrued the calcium content criterion as defining a characteristic of meat, rather than as setting a regulatory limit. FSIS is *not* defining meat in terms of calcium content. Instead, the Agency is using calcium content as a measure for determining that a product has more hard bone (calcified tissue) than is unavoidable as a defect, consistent with current good manufacturing practices.

In the proposed rule, the definition of meat reflects, with certain clarifications, the definition of meat before the 1994 rulemaking, which the 1994 amendments designated as subparagraph (1) of § 301.2(rr). The regulatory requirements for deriving meat by mechanically separating skeletal muscle tissue from the bones of livestock using advances in mechanical meat/bone separation machinery and recovery systems are in revised § 318.24, instead of subparagraph (2) of the definition of meat. As amended by the proposed rule, the definition of meat would specify that ''the portions of bone * * * that normally accompany the muscle tissue * * *'' are the bones found in bone-in products (*e.g.*, T-bone and porterhouse steaks) and that bone includes bone-related components such as bone marrow and spinal cord, as well as hard bone. The statement on the scope of bone (proposed to be designated as subparagraph (2)) would appear after the statement, in the current definition of meat, that meat does not include muscle found in lips, snouts, and ears (the second sentence of the definition, proposed to be redesignated as subparagraph (1)).

The proposed revision of § 318.24 sets out the regulatory requirements that would apply whenever an establishment operator uses advances in mechanical meat/bone separation machinery to recover meat. As amended, paragraph (a) of § 318.24 would provide that:

Meat, as defined in § 301.2 of this chapter, may be derived by mechanically separating

[4] These efforts have included an attempt by pathologists at FSIS's Eastern Laboratory to ''score'' beef neck bone samples collected in the 1996 survey (before bones entered and after they exited meat/bone separation machinery) using criteria that divided bones into three categories (basically (1) recognizable and essentially intact, (2) recognizable with occasional fracturing and/or abrasion/laceration or surface polishing, but no evidence of crushing and minimal bone dust on external surfaces, and (3) not intact with routine fracturing, loss of joint integrity, cartilage, and marrow color, and evidence of crushing and bone dust accumulation external surfaces). (See Attachment 2 to the final report for the criteria.)

[5] A number of establishments utilize a process that includes a final desinewing procedure to remove sinew, tendons, cartilage, and/or incidental bone chips.

skeletal muscle tissue from the bones of livestock using advances in mechanical meat/bone separation machinery and systems that, in accordance with this section, recover meat without crushing, grinding, pulverizing, or otherwise incorporating hard bone or bone-related components.

Adoption of this provision will clarify the regulation by shifting the focus from whether recovery systems ''crush, grind, or pulverize bones'' to the reason why FSIS has disqualified such systems: they incorporate hard bone and related components into the resulting product. This clarification will help prevent debates over how machinery operates (*e.g.*, whether an establishment's use of a particular equipment model crushes bones) and will establish a standard that is not dependent on how machinery operates. For example, if a system were to utilize centrifugal force or suction to recover meat, the bones might not be crushed, ground, or pulverized and the resulting product might have a very low calcium content, even though the action that separates muscle tissue from bones recovers bone-related components other than calcified tissue, thus, resulting in product that is not meat.

FSIS is proposing to revise paragraph (b) of § 318.24 because the Agency no longer can say with confidence that under the compliance requirements adopted in 1994, product derived using advances in meat/bone separation machinery and recovery systems—unlike MS(S)—does not contain powdered bone or constituents of bone such as bone marrow that are not in conformance with the definition and expectation of meat or would render the product adulterated or misbranded (59 FR 62554). After considering additional information on evolving manufacturing practices and product composition, the Agency has tentatively concluded that demonstrating compliance with a limit on calcium content does not suffice to ensure that the resulting product is comparable to meat derived by hand deboning (59 FR 62553). [6]

Paragraph (b) of § 318.4 of the FMIA regulations has long provided that in order for an establishment operator to carry out effectively the responsibility to comply with the FMIA and the regulations thereunder, the operator must institute appropriate measures to assure (among other things) the preparation and labeling of products strictly in accordance with the requirements of those regulations. In the case of advanced meat/bone separation machinery and recovery systems, the Agency now believes that a process control approach is necessary to achieve compliance. Therefore, FSIS is proposing to revise paragraph (b) of § 318.24 by replacing the compliance program parameters prescribed in 1994 (calcium content verification based on lot-by-lot sample analyses) with a requirement that, as a prerequisite to labeling or using product derived by mechanically separating skeletal muscle tissue from livestock bones as meat, an establishment operator must implement and document procedures that ensure that the establishment's production process is in control (proposed introductory text of paragraph (b)). [7]

Proposed paragraph (b)(1) of § 318.24 provides that if any of the noncomplying product provisions of paragraph (c)(1) applies to the resulting product, the production process is not in control. FSIS is not proposing to prescribe how establishment operators maintain control of the production process. The proposed rule would leave each operator free to determine what mix of procedures is best for the particular establishment and to change procedures over time. FSIS is proposing, however, to require that the documentation of an establishment's procedures include, in addition to a description of the procedures themselves, information that substantiates their effectiveness in preventing the incorporation of hard bone and bone-related components, including bone marrow and spinal cord (proposed paragraph (b)(2)). To illustrate the types of documentation that FSIS expects establishments would maintain to comply with this requirement, proposed paragraph (b)(2) includes two examples: information on the characteristics of the product that results when equipment is operated pursuant to manufacturer specifications and records of establishment monitoring and verification activities.

Establishment procedures and substantiating information, along with any other data generated using the process control procedures, would be required to be made available to inspection program personnel (proposed paragraph (b)(3)). FSIS is proposing to amend § 320.1(b)(10) to reflect the fact that, if amended as proposed, § 318.24 would require records that document control of the production process when advanced meat/bone separation machinery and recovery systems are used to produce meat. (See also the record maintenance, retention, and access rules in §§ 320.2, 320.3, and 320.4.)

The purpose of proposed paragraph (c)(1) of § 318.24 is to identify circumstances that would preclude treating product resulting from advanced meat/bone separation machinery and recovery systems as meat. These provisions do not (individually or collectively, or directly or by implication) describe expected or accepted characteristics of meat. Instead, under any of these circumstances, product recovered using mechanical meat/bone separation machinery is not meat.

The proposed rule subdivides paragraph (c)(1) into clauses that identify the three bone-related components addressed therein: (i) bone solids, (ii) bone marrow, and (iii) spinal cord. The Agency is using this format to emphasize that the objective is to make determinations about bone-related components and not, for example, to control the amounts of the essential nutrients calcium and iron, which are used as markers for hard bone and bone marrow, respectively. The inclusion of other markers for bone-related components, such as an alternative method for finding that bone marrow is present in a measurably lower amount or a bone marrow indicator that, unlike proposed clause (ii)(B), does not measure excess iron content, might be appropriate. However, FSIS's tentative judgment is that the criteria in proposed paragraph (c)(1) would provide adequate bases for noncomplying product determinations.

FSIS is proposing, in § 318.24(c)(1)(i), to change the criterion for bone solids from a calcium content limit of no more than 0.15 percent or 150 mg per 100 grams of product, within a tolerance of 0.03 percent or 30 mg per 100 grams of product (*i.e.*, if any analytical result is more than 0.18 percent or 180 mg per 100 grams of product), to a proscription of more than 130.0 mg of calcium per 100 grams. This aspect of the proposal reflects the Agency's tentative judgment that the existing calcium content limit should be reduced because it is higher than the level that is unavoidable under current good manufacturing practices. The Agency also believes that the calcium content limit should be stated as an absolute maximum (*i.e.*, with no tolerance) because accounting for analytical (and any other) variability is a production process control question for industry to address.

[6] For example, based on the levels of iron in beef neck bone products sampled in FSIS's 1996 survey and in both beef and pork products prepared at a number of other official establishments (*i.e.*, levels that are beyond the range of values reported for muscle tissues), bone marrow may be present in products that comply with the calcium content limit. (See, *e.g.*, pages 6, 8, and 9 and Figure 2 (page 23) of the final report on the 1996 survey.)

[7] To avoid possible confusion, FSIS notes that adoption of this proposed requirement would have no effect on the procedures or other labeling rules in part 317 of the regulations.

In developing the proposed calcium cut-off, FSIS evaluated data obtained in the 1996 survey of product recovered from beef neck bones and reviewed other information that has become available since 1994.[8] The Agency found it particularly noteworthy that despite the abrasion of bones and the increase in exposed surfaces that results when neck bones are split prior to meat/bone separation, 90 percent of the samples analyzed in the 1996 survey would have been in compliance under this limit. Nevertheless, FSIS is very interested in receiving additional information on the composition of products recovered from materials other than neck bones before it finally determines whether, and if so, by how much, to reduce the existing calcium content limit. The Agency is especially interested in receiving information on production practices for mechanically separating pork meat from pork bones and, in particular, whether available data support establishing a different, species-specific limit for the calcium content of the resulting product.

FSIS is proposing, in § 318.24(c)(1)(ii) and (c)(1)(iii), to replace the emerging bones criterion (''the bones emerge comparable to those resulting from hand-deboning (*i.e.*, essentially intact and in natural physical conformation such that they are recognizable * * *)'') with noncompliance criteria for bone marrow and spinal cord. Under proposed clause (ii), either of two conditions would constitute failure to comply: the presence of bone marrow in bones entering the recovery system and its absence or presence in a measurably lower amount in bones exiting the recovery system, or an excess iron content in the resulting product, as determined by a specified formula (proposed clauses (ii)(A) and (ii)(B), respectively).

Assessing products for bone marrow content has been controversial, in large part because the composition of marrow and muscle tissues overlap (*i.e.*, they both contain such substances as fat, protein, and cholesterol). This has engendered debates about whether a ''unique'' constituent of marrow can be identified and and its presence reliably measured. What is not in dispute is the Agency's longstanding position that marrow is part of bone, not muscle, and that bone marrow is a feature of MS(S), not meat. This proposal makes that position clearer (proposed subparagraph (2) of the § 301.2(rr) definition of meat). It also shifts the regulatory focus from precisely characterizing a product or product component to determining product noncompliance (proposed § 318.24(c)(1)).

Under a noncompliance approach, the issue becomes the identification of a criterion that can be associated with the presence of bone marrow above an unavoidable defect level. Excess iron is such a criterion,[9] and the Agency has developed a formula for determining excess iron content. Using data collected in FSIS's 1996 survey and other data (from both the literature and industry members) on the relative amounts of iron and protein in muscle trimmed by hand and in product resulting from the use of advanced mechanical meat/bone separation machinery to recover meat from beef neck bones, as sampled in the 1996 survey, the Agency derived general values to represent the ratio of iron content to protein content in beef and in pork. The beef value, 0.067, is based on samples collected in the 1996 survey. The pork value, 0.034, is based on USDA Handbook 8 and other reported data indicating that the ratio of iron content to protein content in pork is half that of the ratio in beef. FSIS then used these values to calculate a figure that represents excess iron: more than 1.80 mg of iron per 100 grams of product.

Under proposed clause (ii)(B), unless an establishment's operator has verified and documented an alternative value for the ratio of iron content to protein content (as explained below), a difference of more than 1.80 between a product's iron content and its protein content multiplied by 0.067 or 0.034 constitutes noncompliance. (In other words, when [iron content—(protein content x 0.067)] > 1.80 mg per 100 grams of beef product or when [iron content—(protein content x 0.034)] > 1.80 mg per 100 grams of pork product, there is noncompliance.) Almost 40 percent of the samples in the 1996 survey of product recovered from beef neck bones would not have been in compliance under the standard proposed for beef products. Given the significant amounts of marrow in beef neck bones and the exposure of additional surface area when neck bones are split prior to meat/bone separation, this finding indicates that unless operators control the production process, primarily by controlling the pressure applied by advanced recovery systems, they can recover bone marrow. A histological examination of the 1996 survey samples of products that were the result of hand trimming and those that were the result of mechanical separation from neck bones, for hematopoietic cells (blood cell precursors), supports the Agency's tentative conclusion that a large proportion of the latter included bone marrow (see pages 4, 6, and 10 of the final report).[10]

FSIS notes that the iron content of samples collected in the 1996 survey was determined using a hydrochloric acid wet ash method. This method is known to recover less iron than two other reliable methods for determining iron content: the sulfuric acid wet ash method and the dry ash method. The Agency is interested in receiving comments on its tentative conclusion that despite differences in the amounts recovered, clause (ii)(B) of § 318.24 need not address iron methodology.

FSIS recognizes that values based on the specific carcass part used in an advanced recovery system would more accurately represent the iron to protein ratio of meat from that part. Therefore, the proviso in proposed clause (ii)(B) states that when the operator of an establishment has verified and documented the ratio of iron content to protein content in the skeletal muscle tissue attached to bones prior to their entering the recovery system, based on analyses of hand-trimmed samples, that value is to be substituted for the multiplier 0.067 or 0.034 (as applicable) with respect to product that the establishment mechanically separates from those bones (*e.g.*, product derived by mechanically separating skeletal muscle tissue from neck bones). Addressing the use of alternative values clearly sets out when a noncompliance determination is to be based on an establishment's own value. This provision would assure that FSIS acknowledges the product-specific values that an establishment has elected to use in ensuring its production process is in control.

FSIS wishes to emphasize that the proposed rule does not prescribe how

[8] See, for example, the industry data submitted to FSIS by the American Meat Institute (''AMR Research Update,'' July 16, 1997) and the Cargill Animal Nutrition & Meat Sector (''Advanced Meat (Poultry) Recovery System,'' August 25, 1997, cover letter to Daniel L. Engeljohn, FSIS).

[9] Research and other reports supporting the position that product resulting from advanced meat/bone separation machinery has a higher iron content than meat prepared by hand trimming include FSIS's 1996 survey and a special committee report prepared in response to consumer concerns by the American Meat Science Association (''Advanced meat recovery systems: A scientific review of the status, with conclusions,'' AMSA, 444 North Michigan Avenue, Chicago Illinois 60611; May 19, 1997).

[10] FSIS scientists conducted this examination because hematopoietic cells have been identified as an indicator of bone marrow. The results confirm the potential usefulness of hematopoietic cells in identifying the presence of bone marrow, and the Agency is now considering volumetric hematopoietic cellular residue and other possible measures of bone marrow content.

establishment operators ensure that they are achieving process control. If adopted, operators could utilize whatever techniques work best for them. Among other things, they might wish to pursue use of pH (potential of hydrogen, a measure of the acidity or alkalinity of a solution), hematopoietic cell concentration, or other variables that have been investigated as indices of bone marrow.[11]

The provisions of the proposed rule do not address cholesterol content, which is found in widely varying amounts in livestock carcass tissues. However, if manufacturers improve the effectiveness of processing controls in preventing the recovery of bone marrow, along with skeletal muscle tissue, FSIS would expect to see some reduction in the cholesterol content of the resulting product, given the higher cholesterol content of bone marrow as compared with muscle tissues and the evidence in the 1996 survey that bone marrow has been incorporated in product derived by mechanically separating muscle from beef neck bones.

Under proposed clause (iii), either of two conditions would constitute failure to comply: the presence of spinal cord in bones entering the recovery system and its absence or presence at a lower level in bones exiting the recovery system or the identification of central nervous system tissue in the product. Because the Agency does not view any level of spinal cord as consistent with defects anticipated when muscle is trimmed from bones by hand, the criterion in the first portion of this provision is presence at a lower level.

During the 1996 survey, the Agency began adapting existing technology for identifying central nervous system tissue based on histological examination of prepared samples to determine whether characteristic features of central nervous system tissue were present (see pages 4, 6, and 10 of the final report). Work on this methodology, which FSIS has shared with industry members, has proceeded to the point where the Agency is confident that the information that the method yields is useful in evaluating the products of advanced mechanical meat/bone separation machinery, but it has not yet been published in a peer reviewed journal. (FSIS generally uses published methods to determine whether there has been a violation of law.)

[11] See, *e.g.*, K. Pickering, *et al.*, Investigation of Methods to Detect Mechanically Recovered Meat in Meat Products—IV: Immunology, Meat Science, 40:327–36 (1995); R.A. Field and P. Arasu, A simple method for estimating amount of red marrow present in mechanically deboned meat, J. Food Sci., 46:1622 (1981).

Adoption of the proposed rule also would clarify what now appears to be a requirement to market product not in compliance with the calcium content limit as MS(S) (last sentence of current § 318.24(b)(1)). Under proposed paragraph (c)(2) of § 318.24, if product that may not be labeled or used as meat meets the requirements of § 319.5(a) (the MS(S) definition and standard), it may bear the name ''Mechanically Separated (Species)''.

In view of comments received in response to the 1996 notice, the Agency wishes to note two additional points about the role of this rulemaking, as opposed to other FSIS initiatives. First, undertaking this rulemaking is consistent with the philosophy underlying the modernization of FSIS's regulatory system and not, as some have asserted, contrary to the Agency's efforts to focus on food safety concerns. FSIS's decisions about how best to utilize Agency resources in no way abrogate industry members' responsibility to comply with statutory requirements and prohibitions, including those mandated to protect the public against products that are misbranded or economically adulterated. Moreover, the amendments in this proposed rule are designed to further the Agency's objective of shifting from a command-and-control approach that prescribes how industry members conduct their operations to a standard-setting approach under which industry members are responsible for achieving compliance and FSIS focuses on verifying the effectiveness of an establishment's processes and process controls.

Second, the amendments that FSIS is proposing to increase the assurance that products marketed as meat do not include spinal cord are not intended as a response to concerns that some have expressed about spongiform encephalopathies. Available data indicate that the United States is bovine spongiform encephalopathy (BSE) free. The Agency will continue its extensive monitoring and participation in USDA and interagency efforts to investigate the public health questions raised by evidence of the transmissibility of BSE. If, as a result, FSIS determines that further regulatory action is needed to protect the public health, it will address the incorporation of central nervous system tissue and other carcass components of potential concern, if any, in the range of animal food products in which they may be found.

Future Agency Action

As noted above, the Agency is reevaluating how it regulates other types of operations that are used to manufacture meat and poultry trimmings from various starting materials and expects that, in future rulemakings, it will apply a process control-performance standards approach to those operations as well. The areas that FSIS expects to address include the development of criteria for the use of meat or poultry ingredients in formulating livestock products and poultry products (as beef, chicken meat, turkey, *etc.*) and criteria for distinguishing between these ingredients and ''byproducts'' (including, *e.g.*, technology dependent requirements and nutrition-related standards).

This effort is part of a comprehensive review of current regulatory requirements and their implementation by FSIS personnel. To achieve the objectives of a modernized regulatory system, FSIS plans to move from a command-and-control approach toward an approach that establishes the standards that industry must meet and provides appropriate flexibility in how they are to be achieved or satisfied.

FSIS also plans to consolidate the FMIA regulations (9 CFR chapter III, subchapter A) and the PPIA regulations (9 CFR chapter III, subchapter C). The Agency believes that this will provide a vehicle for reconsidering the current differences between these sets of regulations. Unless there is a basis, in the statutes or the regulated practices or products, for different requirements, FSIS intends to implement regulatory requirements that do not distinguish between livestock and poultry product establishments or their products.

Executive Order 12866 and Effect on Small Entities

FSIS has determined that this proposed rule is not a significant regulatory action under the criteria set forth in E.O. 12866 because it will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or other rights and obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866. The proposed rule would clarify the regulations and supplement the rules for assuring compliance. Adoption of the

proposed amendments to the definition of meat in § 301.2(rr) would not change the scope of the products that are covered by the definition (in terms of their characteristics or composition). However, FSIS believes that replacing the emerging bones criterion with noncompliance criteria for bone-related components will increase the assurance that, as stated in the 1994 final rule, product marketed as meat ''conforms to the definition of 'meat' because it has the functional and chemical characteristics of meat; there are no powdered bone or constituents of bone, *e.g.*, bone marrow, that are not in conformance with the definition and expectation of meat * * *'' (59 FR 62554).

To prevent noncompliance based on bone marrow content, operations utilizing starting materials that include marrow must control the production process, primarily by controlling the pressure applied by advanced recovery systems. Based on the 1996 survey results, the Agency anticipates that some operations would achieve compliance by reducing current pressure levels, which would result in a small reduction in yield. However, as noted above, the Agency's position that marrow is part of bone and that bone, including bone marrow, is a feature of MS(S), not meat, is a longstanding one.

Controlling the pressure applied also would minimize the effect, if any, of the proposed change in the noncompliance criterion for bone solids. The proposal to reduce the level of calcium (used as a measure of bone solids) reflects the Agency's belief that the existing calcium content limit does not ensure that manufacturers limit bone solids to an unavoidable defect level, as evidenced by the levels currently achieved. If FSIS adopts a rule that lowers the amount of calcium that constitutes noncompliance, its decision will be reflective of information on what operators using good manufacturing practices and controlling their production processes already can and do achieve.

Adoption of a requirement to implement and document procedures that ensure the production process is in control is likely to result in some increase in operators' current expenditures.[12] However, the Agency has long required, in § 318.4(b), that to carry out effectively the responsibility to comply with the FMIA and the regulations thereunder, an establishment's operator must institute appropriate measures to assure the preparation and labeling of products strictly in accordance with regulatory requirements. FSIS now believes that a process control approach is necessary to achieve compliance. Moreover, the proposed rule would replace a prescriptive compliance program for verifying calcium content (including lot-by-lot sample analyses) with a performance standard (preventing the incorporation of hard bone and bone-related components).

In addition to the limited nature of the amendments and the marginal increase in anticipated costs, the Agency expects that it will continue to be large firms that are interested in utilizing advanced meat/bone separation machinery. Therefore, FSIS also certifies that if adopted, this proposed rule will not have a significant economic impact on a substantial number of small entities. Accordingly, as provided in section 605 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), sections 603 and 604 do not apply.

Executive Order 12898

FSIS has considered potential impacts of this proposed rule on environmental and health conditions in minority and low-income communities pursuant to E.O. 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations). Adoption of the proposed rule would not require federally inspected establishments to relocate or alter their operations in ways that could adversely affect the public health or environment in these communities. Nor would it exclude any persons or populations from participation in FSIS programs, deny any persons or populations the benefits of FSIS programs, or subject any persons or populations to discrimination because of their race, color, or national origin.

Executive Order 12988

FSIS has reviewed this proposal as provided in E.O. 12988 (Civil Justice Reform). Section 408 of the FMIA (21 U.S.C. 678) preempts various actions by States, territories, and the District of Columbia. They cannot impose requirements with respect to the premises, facilities, or operations of federally inspected establishments that are in addition to or different than those made under the FMIA, except that they may impose recordkeeping and other access and examination requirements if consistent with section 202 of the FMIA (21 U.S.C. 642). They also cannot impose marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under the FMIA with respect to articles prepared at such establishments. They may, however, consistent with the FMIA's requirements, exercise concurrent jurisdiction over articles that the FMIA requires to be inspected, for the purpose of preventing the distribution of adulterated or misbranded food which is outside of federally inspected establishments or, in the case of imported articles, which are not at federally inspected establishments or after their entry into the United States.

The proposal specifies how, if adopted, the amendments would change current regulations. In other respects, regulatory requirements and procedures (including the rules for directing that the use of labeling be withheld under section 7(e) of the FMIA (21 U.S.C. 607(e)) are unchanged. If adopted, the amendments would not apply retroactively.

Paperwork Reduction Act

FSIS has reviewed the collections of information affected by this proposed rule under the Paperwork Reduction Act (44 U.S.C. chapter 35). The proposed revision of paragraph (b) of § 318.24 would replace the calcium content sampling and records requirements, previously approved by the Office of Management and Budget (OMB) under control number 0583–0095, with a requirement to implement and document procedures that ensure the production process is in control. If FSIS adopts this portion of the proposed rule, it will request that OMB replace the 15,600 burden hours for § 318.24(b) calcium content sampling and recordkeeping with 13,815 burden hours for documenting process control.

List of Subjects

9 CFR Part 301

Meat and meat products.

9 CFR Part 318

Meat and meat products, Meat inspection, Records.

9 CFR Part 320

Meat inspection, Records.

For the reasons set forth above, the Food Safety and Inspection Service is proposing to amend 9 CFR chapter III as follows:

PART 301—TERMINOLOGY

1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, and 2.53.

In § 301.2, paragraph (rr) is revised to read as follows:

[12] A copy of the Agency's 1994 economic impact analysis, which assumed the annual cost of calcium content monitoring to be $5,000 per meat/bone separation machine, is available from the FSIS Docket Clerk.

§ 301.2 Definitions.

* * * * *

(rr) *Meat.* The part of the muscle of any cattle, sheep, swine, or goats that is skeletal or that is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels that normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.

(1) Meat does not include the muscle found in the lips, snout, or ears.

(2) Bone includes hard bone and related components such as bone marrow and spinal cord.

* * * * *

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

3.–4. The authority citation for part 318 is revised to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, and 2.53.

5. Section 318.24 is revised to read as follows:

§ 318.24 Product prepared using advanced meat/bone separation machinery; process control.

(a) *General.* Meat, as defined in § 301.2 of this chapter, may be derived by mechanically separating skeletal muscle tissue from the bones of livestock using advances in mechanical meat/bone separation machinery and systems that, in accordance with this section, recover meat without crushing, grinding, pulverizing, or otherwise incorporating hard bone or bone-related components.

(b) *Process control.* As a prerequisite to labeling or using product derived by mechanically separating skeletal muscle tissue from livestock bones as meat, the operator of an establishment must implement and document procedures that ensure the establishment's production process is in control.

(1) The production process is not in control if any provision of paragraph (c)(1) of this section applies to the resulting product.

(2) The documentation must include a description of the procedures that the establishment has implemented and information that substantiates the effectiveness of these procedures to prevent the incorporation of hard bone and bone-related components, including bone marrow and spinal cord, into the resulting product (*e.g.*, information on the characteristics of resulting product when equipment is operated pursuant to manufacturer specifications; records of establishment monitoring and verification activities).

(3) The establishment must make available to inspection program personnel the documentation described in paragraph (b)(2) of this section and any other data generated using these procedures.

(c) *Noncomplying product.* (1) Notwithstanding any other provision of this section, product that is recovered using mechanical meat/bone separation machinery is not meat under any one or more of the following circumstances.

(i) *Bone solids.* The product's calcium content is more than 130.0 mg per 100 grams.

(ii) *Bone marrow.* (A) The product includes more than a negligible amount of bone marrow, as determined by the presence of bone marrow in bones entering the recovery system and its absence or presence in a measurably lower amount (*e.g.*, by weight) in bones exiting the recovery system.

(B) The difference between the product's iron content and the product's protein content multiplied by 0.067 for a beef product or by 0.034 for a pork product is more than 1.80 mg per 100 grams (*i.e.*, [iron content—(protein content x 0.067)] >1.80 mg per 100 grams of beef product or [iron content—(protein content x 0.034)] >1.80 mg per 100 grams of pork product) (as a measure of excess iron from bone marrow): *Provided,* That when the operator of an establishment has verified and documented the ratio of iron content to protein content in the skeletal muscle tissue attached to bones prior to their entering the recovery system, based on analyses of hand-trimmed samples, that value is to be substituted for the multiplier 0.067 or 0.034 (as applicable) with respect to product that the establishment mechanically separates from those bones.

(iii) *Spinal cord.* The product includes spinal cord, as determined by the presence of spinal cord in bones entering the recovery system and its absence or presence at a lower level in bones exiting the recovery system or by the identification of central nervous system tissue in the product.

(2) If product that may not be labeled or used as meat in accordance with this section meets the requirements of § 319.5(a) of this chapter, it may bear the name ''Mechanically Separated (Species)''.

PART 320—RECORDS, REGISTRATION, AND REPORTS

6. The authority citation for part 320 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, and 2.53.

§ 320.1 [Amended]

7. Paragraph (b)(10) of § 320.1 is amended by removing ''of calcium content in meat derived from'' and adding, in its place, ''documenting control of the production process using''.

Done at Washington, DC, on April 3, 1998.

Thomas J. Billy,

Administrator.

[FR Doc. 98–9681 Filed 4–10–98; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 563

[No. 98–35]

RIN 1550–AB16

Transactions with Affiliates; Reverse Repurchase Agreements

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office of Thrift Supervision (OTS) is proposing to revise its regulations on transactions with affiliates. Specifically, the OTS proposes to clarify that it will treat reverse repurchase agreements, with one limited exception, as loans or other extensions of credit for the purposes of section 11(a)(1)(A) of the Home Owners' Loan Act (HOLA). Therefore, a savings association generally may not enter into a reverse repurchase agreement with an affiliate that is engaged in non-bank-holding company activities.

DATES: Comments must be received on or before June 12, 1998.

ADDRESSES: Send comments to Manager, Dissemination Branch, Records Management and Information Policy, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, Attention Docket No. 98–35. These submissions may be hand-delivered to 1700 G Street, NW., from 9:00 a.m. to 5:00 p.m. on business days; they may be sent by facsimile transmission to FAX Number (202) 906–7755 or by e-mail public.info@ots.treas.gov. Those commenting by e-mail should include their name and telephone number. Comments will be available for