Dated: October 26, 2001.

John Ashcroft,

Attorney General.

[FR Doc. 01–27447 Filed 10–29–01; 1:51 pm]

BILLING CODE 4410–10–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 319, and 381

[Docket No. 01–016DF]

Use of Transglutaminase Enzyme and Pork Collagen as Binders in Certain Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Direct final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its meat inspection regulations to permit the use of pork collagen and transglutaminase enzyme (TG enzyme), in limited amounts, as binders in certain standardized meat food products. FSIS also is amending its poultry products inspection regulations to permit the use of TG enzyme, in limited amounts, as a binder in certain standardized poultry products. Additionally, FSIS is amending the meat and poultry inspection regulations to require that, when TG enzyme is used to fabricate or reform cuts of meat or poultry, the resulting product bear labeling to indicate that it has been formed from pieces of whole muscle meat, or that it has been reformed from a single cut. FSIS is proceeding with this direct final rule in response to petitions submitted to the Agency by Ajinomoto, U.S.A., Inc. and AMPC, Corp.

DATES: This rule will be effective December 31, 2001 unless FSIS receives written adverse comments within the scope of this rulemaking or written notice of intent to submit adverse comments within the scope of this rulemaking on or before November 30, 2001. If FSIS receives adverse comments, a timely withdrawal will be published in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit adverse comments or notice of intent to submit adverse comments within the scope of this rulemaking to: FSIS Docket Clerk, Docket #01–016DF, Room 102, Cotton Annex, 300 C Street, SW., Washington, DC 20250–3700. Reference materials cited in this document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 205–0279

SUPPLEMENTARY INFORMATION:

Background

Ajinomoto and AMPC Petitions

On May 5, 1999, Hogan and Hartson, L.L.P. filed a petition with FSIS on behalf of its client, Ajinomoto, USA, Inc. (Ajinomoto), requesting that the Agency amend its regulations to allow the use of TG enzyme, at usage levels of up to 65 ppm of product formulation, to improve texture and cooking yields in various standardized meat and poultry products. Ajinomoto also requested that FSIS permit TG enzyme to be used as a protein cross-linking agent, at usage levels of up to 65 ppm, to fabricate or reform cuts of meat. When TG enzyme is used to fabricate or reform cuts of meat, Ajinomoto requested that the resulting product be distinguished from its non-fabricated counterpart through terms such as ''formed'' or ''reformed'' as part of the product name (*e.g.* ''formed beef tenderloin''), as opposed to a statement that declares the presence of the enzyme as part of the product name (*e.g.* ''beef tenderloin formed with water and transglutaminase enzyme'').

TG enzyme is derived from a non-toxigenic and non-pathogenic strain of *Streptoverticillium mobaraense* and functions by catalyzing the formation of a covalent bond between the glutamine and lysine side residues of proteins. There are no current allowances in the FSIS regulations or those of the Food and Drug Administration (FDA) for the use of TG enzyme as a binder or protein cross-linking agent in standardized meat or poultry products.

In a previous petition submitted in June 1997, Ajinomoto requested that FSIS permit the use of TG enzyme in both standardized and non-standardized meat and poultry products. In support of the petition, Ajinomoto submitted data to support the generally recognized as safe (GRAS) status of TG enzyme for use as a cross-linking agent in meat and poultry products at levels of up to 65 ppm. As part of its review of the petition, FSIS asked FDA to evaluate the data submitted by Ajinomoto on the safety of TG enzyme for this proposed use. In January 1998, FDA sent a letter to FSIS that said that, although it has not made a determination regarding the GRAS status of any use of this enzyme, FDA would not challenge, at this time, Ajinomoto's conclusion that TG enzyme is safe under the proposed conditions of use.

Based on the findings of FDA's evaluation, described above, and the technical data provided by Ajinomoto, FSIS concluded that TG enzyme was suitable for use in non-standardized meat and poultry products, and in meat and poultry products that have been formulated to reduce sodium or fat content. Thus, the Agency permits the use of TG enzyme, at levels of up to 65 ppm, in such products, provided that the products are identified by a truthful descriptive designation, such as ''low fat pork sausage, water and TG enzyme product.''

Although FSIS determined that TG enzyme was suitable for use in non-standardized meat and poultry products, and in meat and poultry products that have been formulated to reduce sodium or fat content, in its review of the 1997 petition, the Agency also found that Ajinomoto submitted insufficient data on the suitability of the use of TG enzyme in standardized meat and poultry products. FSIS informed Ajinomoto that in order to permit the use of TG enzyme in standardized products, the Agency must pursue rulemaking to amend the regulatory standards of identity. FSIS suggested that Ajinomoto submit a petition to request that the Agency amend the individual meat and poultry product standards to provide for the use of TG enzyme. The Agency also informed Ajinomoto that such a petition must include technical data to establish the suitability of TG enzyme for use in standardized meat and poultry products. In response, Ajinomoto submitted the May 5, 1999, petition, to which this rulemaking responds.

In support of its most recent petition, Ajinomoto submitted numerous published studies on the efficacy of TG enzyme in cross-linking muscle proteins. FSIS determined that the data demonstrate that TG enzyme is effective in improving texture by increasing elasticity and improving cooking yields in standardized meat sausage products, standardized restructured meat products, standardized ''roast beef parboiled and steam roasted'' meat products, and standardized poultry rolls. The Agency also determined that TG enzyme is effective in binding pieces of whole muscle meat to fabricate or reform cuts of meat. FSIS concluded that the data demonstrate efficacy at 65 ppm. However, FSIS found that the petition contained insufficient data to support the use of TG enzyme in

standardized poultry products other than poultry rolls.

In support of its request that cuts of meat fabricated or reformed using TG enzyme be identified as ''formed'' or ''reformed'' in conjunction with the product name, Ajinomoto claimed that TG enzyme does not change the essential character of a meat product. According to the data presented by Ajinomoto, TG enzyme functions to fuse together muscle tissue, and that whole muscle tissues fused together with the TG enzyme have the same taste, aroma, nutritional profile, and other properties as untreated whole muscle tissue. Thus, Ajinomoto argued, the primary difference between a cut of meat formed with TG enzyme and an untreated cut will be the shape or size of the final product.

Because muscle fibers treated with TG enzyme will not be aligned as they would be naturally, the Agency does not agree that TG enzyme does not affect the essential character of a product. However, the Agency does agree that, because the primary difference between a cut of meat formed with TG enzyme and an untreated cut is the shape of the product, special labeling to alert the consumer to the presence of the TG enzyme in the product, such as ''beef tenderloin formed with water and transglutaminase enzyme,'' is not necessary. Therefore, in this direct final rule, the Agency is requiring that products that are fabricated using TG enzyme bear the term ''formed'' or ''reformed'' in conjunction with product name. The words ''formed'' and ''reformed'' are appropriate terms to identify these products because these terms reveal the material fact that multiple pieces of meat have been formed to look like a solid piece of meat. Otherwise, consumers could be misled. The product must also declare the presence of TG enzyme in the list of ingredients on the product's label, as required by 9 CFR 317.2(f)(1) and 381.118(a)(1).

On September 27, 1999, AMPC, Inc., petitioned FSIS to amend its regulations to allow the use of pork collagen, a connective tissue protein, as a binder in sausage as provided in 9 CFR Part 319, at usage levels of up to 3.5% of product formulation. In addition to sausage as provided in 9 CFR Part 319, AMPC requested that FSIS allow the use of pork collagen as a binder in other standardized meat and poultry products, such as cured pork products, luncheon meat, meat food entrée products, pies, turnovers, meat snacks, hors d'oeuvres, pizza and specialty items, meat salads, meat spreads, barbecued meats, poultry breakfast sausages, and canned, frozen, or dehydrated meat food products. There are no current allowances in the FSIS regulations for the use of pork collagen as a binder in standardized meat or poultry products.

Before petitioning FSIS, AMPC submitted a GRAS Notification to FDA concerning the use of pork collagen as a binder in meat products. After consulting with FSIS, FDA sent a letter to AMPC on July 29, 1999, that said that FDA ''has no questions at this time regarding the conclusion of AMPC that pork collagen is GRAS for use as a binder and purge reducing additive in meat and meat type products at a level of 1–3.5% '' (GRAS Notice No. GRN 000021). FDA instructed AMPC to consult with FSIS regarding the suitability of the use of pork collagen in meat and poultry products, and the acceptability of use within the context of the Federal meat and poultry products inspection regulations.

AMPC has conducted research to support the efficacy of pork collagen as a binder in sausages and submitted data with the petition. After evaluating the data submitted by AMPC, FSIS determined that the data demonstrate that pork collagen is effective at reducing purge and improving cooking yields in those meat sausages whose standards permit binders, in certain standardized cured pork products, and in non-standardized meat and poultry products. FSIS also determined that the data demonstrate efficacy at 3.5% of the product formulation. Thus, the Agency permits the use of pork collagen, at the specified levels, in non-standardized meat and poultry products, provided that these products are identified by a truthful descriptive designation, such as ''low fat pork sausage, water and pork collagen.''

However, to permit the use of pork collagen in standardized meat and poultry products, the Agency must conduct rulemaking to amend the individual product standards. Therefore, in response to AMPC's petition, FSIS is publishing this direct final rule to amend the standards of identity for certain meat sausages and certain standardized cured pork products. The Agency is not amending other product standards in this rulemaking because it found that the petition contained insufficient data to support the suitability of pork collagen for use in standardized poultry products.

Current Regulatory Requirements

In order to permit the use of a food ingredient in the production of meat or poultry products, FDA, in consultation with FSIS, assesses the safety of the ingredient's proposed use, while FSIS evaluates its efficacy and suitability for use in meat and poultry products. At the time that AMPC and Ajinomoto submitted their petitions, substances permitted for use in the production of meat products were listed in the chart of approved substances contained in former 9 CFR 318.7(c)(4), and substances permitted to be used in the production of poultry products were listed in the chart of approved substances contained in former 9 CFR 381.147(f)(4). Therefore, in its petition, Ajinomoto requested that FSIS amend the chart of substances in former §§ 318.7(c)(4) and 381.147(f)(4) to include the acceptable use of TG enzyme as a binder and cross-linking agent for sausage and other standardized meat and poultry products. Likewise, in its petition, AMPC requested that FSIS amend the chart of substances in former §§ 318.7(c)(4) and 381.147(f)(4) to include the acceptable use of pork collagen as a binder for sausage and other standardized meat and poultry products.

On December 23, 1999, FSIS published a final rule, ''Food Ingredients and Sources of Radiation Listed or Approved for Use in Meat and Poultry Products,'' designed to improve the efficiency of the procedures used by FSIS and FDA to review and approve the use of food ingredients and sources of radiation in the production of meat and poultry products (64 FR 72168). Under the new regulations, rather than listing substances approved for use in the production of meat and poultry products in the chart of substances contained in former 9 CFR 318.7(c)(4) and former 9 CFR 381.147(f)(4), FDA now lists food ingredients and sources of radiation that are safe for specific use in the production of meat and poultry products in its regulations in title 21 of the CFR. 9 CFR parts 310, 318, 319, and 381 of the FSIS regulations were amended to include appropriate cross-references to title 21 listings of substances and sources of radiation approved for use in meat and poultry products. In the final rule, FSIS also created one list of food ingredients approved for use in the production of meat and poultry products by combining the listing contained in former section 318.7(c)(4) with the listing contained in former section 381.147(f)(4) and moving the combined listing to section 424.21(c). The final rule became effective on January 24, 2000.

Because FDA now lists food ingredients and sources of radiation approved for use in the production of

meat and poultry products in its regulations, FSIS has stated that it will limit substance-specific rulemakings to those necessary to establish specific prohibitions or limitations on the use of food ingredients in the production of meat or poultry products. Such rulemakings are necessary when a standard of identity or composition prohibits or limits the use of an ingredient. In these instances, the standard of identity must be amended to include the permitted use of the ingredient. FSIS does not intend to add any new substances to the chart contained in 9 CFR 424.21(c).

As previously mentioned, FSIS currently permits TG enzyme and pork collagen to be used in non-standardized meat and poultry products, such as meat links or patties, and modified versions of traditional products, such as ''low fat pork sausage, water, and pork collagen product,'' and ''reduced fat breakfast sausage with transglutaminase enzyme,'' provided that these products are identified by a truthful descriptive designation (9 CFR 317.2(c)(1), 317.2(e) and 381.117(a)). However, according to the petitioners, these descriptive designations may confuse some consumers or may cause some consumers to believe that the product identified by the descriptive designation is inferior to the traditional standardized version. Thus, the petitioners requested that, when TG enzyme or pork collagen is used as a binder in certain standardized products, these products be permitted to be identified by a standardized term, such as ''hotdogs'' or ''breakfast sausage.''

The Final Rule

FSIS is amending its meat inspection regulations and poultry products inspection regulations to permit the use of TG enzyme as a binder at up to 65 ppm of product formulation in sausages as provided in 9 CFR part 319, in fabricated steaks under 9 CFR 319.15(d), in ''roast beef parboiled and steam roasted'' under 9 CFR 319.81, and in poultry rolls under 9 CFR 319.81. FSIS is also amending its meat inspection regulations to permit the use of pork collagen as a binder at up to 3.5% of product formulation in sausages whose standards currently permit binders as provided in 9 CFR part 319 and cured pork products as provided in 9 CFR 319.104. Under § 319.104, binders are only permitted in certain cured pork products, such as ''Ham Water Added,'' ''Ham and Water Product-X% of Weight is Added Ingredients,'' and ''Ham with Natural Juices.'' Under this direct final rule, the use of pork collagen is also limited to those particular cured pork products.

Because it no longer adds new substances to the list of approved substances codified at 9 CFR 424.21(c), the Agency is amending the standards of identity for sausage at 9 CFR 319.140, fabricated steaks at 9 CFR 319.15(d), ''roast beef parboiled and steam roasted'' at 9 CFR 319.81, certain cured pork products at 9 CFR 319.104, and poultry rolls at 9 CFR 381.159 to permit the use of either TG enzyme, pork collagen, or both of these substances at the specified levels. The Agency is revising the standards of identity for the sausages that currently permit the use of binders, such as ''breakfast sausage'' (9 CFR 319.143), ''frankfurter,'' ''frank,'' ''furter,'' ''hotdog,'' ''weiner,'' ''vienna,'' ''bologna,'' ''garlic bologna,'' ''knockwurst,'' and similar products (9 CFR 319.180), and ''cheesefurters'' and similar products (9 CFR 319.181), to cross reference 319.140 for the purpose of determining which binders are permitted for use in these products and at what levels. The standards of identity for ''braunschweiger'' (9 CFR 319.182(a)) and ''liver sausage'' or ''liverwurst'' (9 CFR 319.182(b)) permit the addition of binders and contain a cross reference to § 319.140 for purposes of determining the permissible use of these substances in these products. Therefore, there is no need to change these product standards.

The Agency is also amending 9 CFR 317.8(b) of the meat inspection regulations to require that, when transglutaminase enzyme is used to fabricate or reform a cut of meat, the resulting product's labeling include a statement to indicate that the product has been ''formed'' or ''reformed'' as part of the product name. The Agency has determined that such labeling is necessary because TG enzyme alters the essential character of a product by making multiple cuts of meat or pieces of muscle tissue appear to be one intact cut or piece of meat, which could mislead consumers about the nature of this type of product. The Agency has determined that the terms ''formed'' and ''reformed'' are appropriate descriptive terms. Although it must be revealed in the ingredients statement, the presence of TG enzyme need not be disclosed as part of the product name. The labeling of these products must still comply with the requirement that a product that has been prepared by salting, smoking, drying, cooking, chopping, or otherwise must be so described on the label, unless the name of the product implies, or the manner of packaging shows that the product was subject to such preparation (9 CFR 317.2(e)).

The following examples are intended to provide further clarification on the application of the labeling requirements for products that have been fabricated or reformed using TG enzyme. When the surface of two whole beef tenderloins are fused together to create a product with a uniform thickness or portion size, an appropriate name for the product would be ''Formed Beef Tenderloin.'' However, if TG enzyme is used to fuse non-intact pieces of beef tenderloin to form a roll that resembles a tenderloin, an appropriate name would be ''Reformed Beef Tenderloin Pieces.'' When a beefsteak is formed by treating chopped pieces of meat trim with TG enzyme to fuse the pieces together, an appropriate name for this product would be ''Formed Beefsteak, Chopped and Shaped.'' When seam fat is removed from a cut of meat and the cut is then reassembled using TG enzyme, an appropriate name for the product would be ''reformed'' in conjunction with the name of the product, for example, ''Reformed Ribeye Steak.''

The petition did not request that FSIS adopt these labeling requirements for fabricated or reformed poultry products. However, because FSIS has determined that TG enzyme is suitable for use in non-standardized poultry products and modified versions of traditional poultry products, and because it is interested in harmonizing the meat and poultry inspection regulations, the Agency is amending 9 CFR 381.129 to require that the labels of poultry products fabricated or reformed using TG enzyme state that the product has been ''formed'' or ''reformed'' as part of the product name.

Establishments that choose to use TG enzyme or pork collagen in their products will be required to list these substances, in descending order of predominance, in the product's ingredients statement (9 CFR 317.2(f)(1) and 381.118(a)(1)). This will require modification of the product's label and the printing of new product labels.

Because the use of these substances at the level that are being provided for by FSIS is not controversial, and because these substances are permitted in non-standardized products, FSIS expects no adverse comment to result from the changes that it is making in this direct final rule. Therefore, unless the Agency receives written adverse comments within the scope of this rulemaking, or a written notice of intent to submit adverse comments within the scope of this rulemaking, within 30 days, this action will become final 60 days after publication in the **Federal Register**. If written adverse comments within the scope of the rulemaking are received,

the final rulemaking notice will be withdrawn, and the Agency will publish a proposed rulemaking notice that includes a comment period.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. It has been determined to be not significant for purposes of E.O. 12866 and therefore, has not been reviewed by the Office of Management and Budget (OMB).

Effect on Small Entities

This direct final rule will permit the use of TG enzyme and pork collagen in certain standardized meat food products. It also prescribes labeling requirements for meat and poultry products fabricated or reformed using TG enzyme.

The use of these ingredients is voluntary and therefore, the impact of this direct final rule on small establishments is likely to be minimal. FSIS does not believe that any costs associated with changes to labels will be significant. The decision by individual establishments to use these ingredients will be based on their conclusions that the benefits of providing new product to meet consumers' needs outweigh the implementation costs.

Executive Order 12988

This direct final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5, 381.35, and 590.320 through 590.370, respectively, must be exhausted before any judicial challenge of the application of the provisions of this direct final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

Paperwork Requirements

Abstract: FSIS has submitted an emergency information collection request for the paperwork and record keeping requirements in this direct final rule in accordance with the Paperwork Reduction Act. Establishments that choose to use any of the substances permitted by this final rule will have to make changes to their product labels.

Estimate of Burden: Establishments must develop product labels in accordance with the regulations. To receive approval of the labels, establishments must complete FSIS Form 7234–1. FSIS program employees review FSIS Form 7234–1 to ensure that the information on the labels complies with the regulations. FSIS estimates that it will take 60 minutes to design and develop modified product labels in accordance with this direct final rule and 15 minutes to prepare FSIS Form 7234–1 and submit it, along with the sketch label, to FSIS.

Establishments will only need to make the label change once.

Respondents: Meat and poultry product establishments.

Estimated Number of Respondents: 992

Estimated number of Responses per Respondents: FSIS estimates that each establishment will modify one product label.

Estimated Total Annual Burden on Respondents: 1,240 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, Room 109 Cotton Annex., Washington, DC 20250–3700.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to Lee Puricelli, see the address above, and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) Washington, DC 20253.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this direct final rule and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS Web page located at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

List of Subjects

9 CFR Part 317

Food labeling, Meat Inspection.

9 CFR Part 319

Food grades and standards, Food labeling, Meat inspection.

9 CFR Part 381

Food labeling, Poultry and poultry products.

For the reasons discussed in the preamble, FSIS amends 9 CFR Chapter III as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 continues to read as follows:

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

2. Section 317.8 is amended by adding a new paragraph (b)(39) to read as follows:

§ 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

* * * * *

(b) * * *

(39) When transglutaminase enzyme is used to bind pieces of meat to form a cut of meat, or to reform a piece of meat from a multiple cuts, there shall appear on the label, as part of the product name, a statement that indicates that the product has been ''formed'' or ''reformed,'' in addition to other preparation steps, e.g., ''Formed Beef Tenderloin'' or ''Reformed and Shaped Beef Tenderloin.''

* * * * *

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 319.15 is amended by revising paragraph (d) to read as follows:

§ 319.15 Miscellaneous beef products.

* * * * *

(d) *Fabricated steak.* Fabricated beef steaks, veal steaks, beef and veal steaks, or veal and beef steaks, and similar products, such as those labeled ''Beef Steak, Chopped, Shaped, Frozen,'' ''Minute Steak, Formed, Wafer Sliced, Frozen,'' ''Veal Steaks, Beef Added, Chopped—Molded—Cubed—Frozen, Hydrolyzed Plant Protein, and Flavoring'' shall be prepared by comminuting and forming the product from fresh and/or frozen meat, with or without added fat, of the species indicated on the label. Such products shall not contain more than 30 percent fat and shall not contain added water or extenders. Transglutaminase enzyme at levels of up to 65 ppm may be used as a binder. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of fabricated beef steaks only in accordance with the conditions prescribed in paragraph (a) of this section.

* * * * *

5. Section 319.81 is amended by adding the following new sentence after the phrase ''shall not exceed 70 percent of the fresh beef weight'':

''Transglutaminase enzyme at levels of up to 65 ppm may be used as a binder in such product.''

6. Section 319.104 is amended by revising paragraph (d) to read as follows:

§ 319.104 Cured pork products.

* * * * *

(d) The binders provided for use in cured pork products in a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used singly in those cured pork products labeled as ''Ham Water Added,'' ''Ham and Water Product-X% of Weight is Added Ingredients,'' and ''Ham with Natural Juices.'' In addition to the binders referred to in the preceding sentence, the following substances are permitted for use as binders and may be used singly in those cured pork products labeled as ''Ham Water Added,'' ''Ham and Water Product-X% of Weight is Added Ingredients,'' and ''Ham with Natural Juices'': pork collagen at up to 3.5% of the product formulation. Unless their use is provided for in a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, or in this paragraph, these binders are not permitted to be used in combination with another such binder listed for use in cured pork products. When any such substance is added to these products, the substance shall be declared in the ingredients statement by its common or usual name in order of predominance.

* * * * *

7. Section 319.140 is amended by adding the following new sentence after the phrase ''may contain binders and extenders as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B'':

''In addition to the binders and extenders referred to in the preceding sentence, the following two substances may also be used as binders in those sausages in which the use of such class of substances is permitted: pork collagen at up to 3.5% of the product formulation and transglutaminase enzyme at up to 65 ppm of the product formulation.''

8. Section 319.143 is amended by removing the phrase ''§ 318.7(c)(4) of this subchapter'', and adding ''§ 319.140 of this part'' in its place.

9. Section 319.180 is amended by revising paragraph (e) to read as follows

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

* * * * *

(e) Binders and extenders as provided in § 319.140 of this part may be used in cooked sausage that otherwise comply with paragraph (a) or (b) of this section. When any such substance is added to these products, the substance shall be declared in the ingredients statement by its common or usual name in order of predominance.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

11. Section 381.129 is amended by adding a new paragraph (e) to read as follows:

§ 381.129 False or misleading labeling or containers.

* * * * *

(e) When transglutaminase enzyme is used to bind pieces of poultry to form a cut of poultry, or to reform a piece of poultry from a multiple cuts of poultry, there shall appear on the label, as part of the product name, a statement that indicates that the product has been ''formed'' or ''reformed,'' in addition to other preparation steps, e.g., ''Formed Turkey Thigh Roast'' or ''Reformed and Shaped Chicken Breast.''

12. Section 381.159 is amended by revising paragraph (a) to read as follows:

§ 381.159 Poultry rolls.

(a) Binders or extenders may be added in accordance with a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. In addition to the binders referred to in the preceding sentence, the following substances are permitted for use as binders in poultry rolls: transglutaminase enzyme at up to 65 ppm. When binding agents are added in excess of 3 percent for cooked rolls and 2 percent for raw rolls, the common name of the agent or the term ''Binders Added'' shall be included in the name of the product; e.g., ''Turkey Roll-Gelatin Added.''

* * * * *

Done at Washington, DC, on: October 25, 2001.

Thomas J. Billy,

Administrator.

[FR Doc. 01–27264 Filed 10–30–01; 8:45 am]

BILLING CODE 3410–DM–P

FEDERAL HOUSING FINANCE BOARD

12 CFR Part 918

[No. 2001–25]

RIN 3069–AB05

Maintenance of Effort—Minimum Number of Annual Bank Board of Directors Meetings

AGENCY: Federal Housing Finance Board.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Board (Finance Board) is adopting as final, without change, the interim final rule that amended the maintenance of effort provision of its regulations to eliminate the three-year averaging requirement and to reduce the required minimum number of in-person board of directors meetings that a Federal Home