

HOGAN & HARTSON  
L.L.P.

FSIS RECEIVED  
DOCKET ROOM  
01 NOV 03  
Dez  
AM 10:03

(1)

November 30, 2001

MARTIN J. HAHN  
PARTNER  
(202) 637-6926  
MJHAHN@HHLAW.COM

COLUMBIASQUARE  
555 THIRTEENTH STREET, NW  
WASHINGTON, DC 20004-1109  
TEL (202) 637-5600  
FAX (202) 637-5910

FSIS Docket Clerk  
United States Department of Agriculture  
Docket No. 01-016DF  
Room 102, Cotton Annex  
300 12<sup>th</sup> Street, S.W.  
Washington, D.C. 20250-3700

01-016DF  
01-016DF-1  
Martin J. Hahn

**Re: Docket No. 01-016DF; Use of Transglutaminase Enzyme  
and Pork Collagen as Binders in Certain Meat and  
Poultry Products; Direct Final Rule**

We are submitting this comment on behalf of our client, Ajinomoto USA, Inc. (Ajinomoto), in response to the October 31, 2001 Federal Register Notice of Direct Final Rule authorizing the use of microbial transglutaminase (TG) enzyme as a binder in certain meat and poultry products. 66 Fed. Reg. 54912 (Oct. 31, 2001). We note at the outset that Ajinomoto fully supports the rule, which is based on a Petition that the company submitted. We also commend FSIS on its efforts in this rulemaking. This comment seeks to **clarify** and affirm that the Direct Final Rule is intended to allow the use of TG enzyme in cured pork products.

By way of brief background, Ajinomoto submitted Petitions on May 5, 1999 and June 4, 2001, that requested FSIS to amend numerous of its meat and poultry standards to allow for the use of TG enzyme in those products. The June 4, 2001 Petition specifically requested amending the standards for Restructured Meats (9 C.F.R. § 319.15(d)), Roast Beef Parboiled and Steam Roasted (9 C.F.R. § 319.81), Cured Pork Products (9 C.F.R. § 319.1041, Cooked Sausages (9 C.F.R. § 319.180), and Poultry Rolls (9 C.F.R. § 381.159). The June 4, 2001 petition provided efficacy data that supported the use of TG enzyme in each of those standardized products. Specifically, Appendices D through I of the petition provided data from studies establishing the ability of the TG enzyme to cross-link muscle proteins and bind muscle tissue; Appendix K provided data showing that the TG enzyme can increase elasticity, prevent splitting, and improve slicing of hams; and Appendix O provided data showing that the TG enzyme can increase the bond strength and distance to reach peak force when used in cooked ham products. A summary of the efficacy data supporting the proposed amendments appears in Appendix A of the June 4, 2001 petition.

The Direct Final Rule expressly provides for the use of TG enzyme in four standardized products: Restructured Meats (9 C.F.R. § 319.15(d)), Roast Beef Parboiled and Steam Roasted (9 C.F.R. § 319.81), Cooked Sausages (9 C.F.R. § 319.180), and

FSIS Docket Clerk  
November 30, 2001  
Page 2

Poultry Rolls (9 C.F.R. § 381.159). It also sets forth FSIS's finding that the Petition provided inadequate data to support the use of TG in poultry products other than poultry rolls. The direct final rule does not, however, clearly address the use of TG enzyme in cured pork products subject to 9 C.F.R. § 319.104.

When viewed in its entirety, we believe that the administrative record supports a conclusion that FSIS intended to permit the use of TG enzyme in cured pork products subject to 9 C.F.R. § 319.104. As noted above, the Petition expressly requested that the standard of identity for cured pork products be amended to provide for the use of TG enzyme as a binder, and provided data in support of this request. The agency's failure to specifically reject Ajinomoto's request to use the TG enzyme in cured pork products and other language used in the Direct Final Rule indicates that FSIS intended to allow the use of TG in cured pork products.

Although we believe that the agency intended to allow the use of the TG enzyme in cured pork products, the standard of identity for cured pork products does not contain language specifically authorizing the use of TG enzyme. Given the uncertainty created by the language used in the Direct Final Rule, we ask that the agency find some means to clarify that the Final Rule is intended to allow the use of TG enzyme in cured pork products.

Ajinomoto is aware that FSIS policy provides that a Direct Final Rule may not become effective if it is the subject of adverse comments. 59 Fed. Reg. 34375 (July 5, 1994). Comments are considered "adverse" if they suggest that the rule not be adopted or suggest a change in the rule. *Id.* Ajinomoto does not believe that this comment constitutes a "change" that would preclude the rule from becoming effective as anticipated on December 31, 2001 because we are merely seeking a clarification on the scope of the final rule. Should FSIS disagree, we respectfully request that this comment be withdrawn, and that the rule be permitted to take effect as provided in the October 31, 2001 Direct Final Rule.

Ajinomoto appreciates the opportunity to share its comments with FSIS, and commends the agency on its efforts in developing science-based standards that enhance the quality of the food supply.

Sincerely,

  
Martin J. Hahn