

August 16, 2001

Robert Post, Ph.D.
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 112, Cotton Annex
300 12th Street, S.W.
Washington, D.C. 20250-3700

Re: Labeling of Natural or Regenerated Collagen Sausage Casings

Dear Dr. Post:

The Small Business Administration's Office of Advocacy would like to provide you with its position concerning the FSIS's final rule on the labeling of natural or regenerated collagen sausage casings.¹

The Office of the Chief Counsel for Advocacy of the U.S. Small Business Administration was created in 1976 to represent the views and interests of small business in Federal policy making activities. The Chief Counsel (1) participates in rulemakings when necessary to ensure proper representation of small business interests; (2) reports to Congress annually on Federal agency compliance with the Regulatory Flexibility Act (RFA); and (3) works with federal agencies to ensure that their rulemakings reflect the results of an analysis of the impact that their decisions will have on small businesses.

It is the Office of Advocacy's position that the FSIS has failed to comply with the spirit and intent of the RFA in connection with this rule. Advocacy arrived at this conclusion after reviewing the regulatory flexibility analysis provided by the FSIS in accordance with 5 U.S.C. sections 603 and 604, contained in both the proposed rule and the final rule.²

The initial regulatory flexibility analysis contained in the proposed rule failed to comply with 5 U.S.C. section 603.

Section 603 provides, *inter alia*, that the initial regulatory flexibility analysis (IRFA) **shall** contain: a description of and, where feasible, an estimate of the number of small

¹ 66 FR 40843, August 6, 2001.

² The cite for the proposed rule is 62 FR 38220, July 17, 1997.

entities to which the proposed rule will apply; a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record; a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.

In the RFA section of the proposed rule, the FSIS admitted that it “did not currently have all the data necessary for a comprehensive analysis of the effects of this rule on small entities.” FSIS then shifted the burden for determining what, if any, adverse effects the proposed rule would have on small entities by requesting public comment on the issue. The FSIS further stated its belief that “associated labeling costs would be low because manufacturers would be able to defer the development of new labels until their existing stocks of labels were exhausted.”

In contravention of the RFA, FSIS failed to make a good faith effort to obtain the required information for a determination of whether the rule will have any adverse effects on small entities.³ The FSIS also failed to provide any data and/or economic information to substantiate its belief that any associated labeling costs would be minimal.⁴ Lastly, the FSIS failed to provide any significant alternatives and/or exemptions that would minimize any significant economic impact on small entities.⁵

The final regulatory flexibility analysis (FRFA) contained in the final rule failed to comply with 5 U.S.C. section 604.

The FSIS violated section 604 of the RFA, which contains information on when a FRFA is required and provisions on what should be contained therein. This conclusion is buttressed by the fact that the FSIS simply cut and pasted the information contained in the proposed rule’s IRFA and placed it in the RFA section in the final rule. To the extent that the FSIS intended the information contained in the RFA section of the final rule to serve as a FRFA, it fell short of the requirements of section 604.⁶ In large measure the RFA section of the final rule fails to comply with the RFA for the same reasons that the IRFA was inadequate as contained in the proposed rule. The FRFA lacks information on: any public comments received in response to the IRFA; a description of and an estimate of the number of small entities to which the rule will apply; a description of the reporting

³ See 5 U.S.C. §603(b)(3).

⁴ See 5 U.S.C. §603(b)(4).

⁵ See 5 U.S.C. §603(c).

⁶ 5 U.S.C. §604(a) requires an agency to prepare a FRFA when the agency is required by law to publish a notice of proposed rulemaking.

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and recordkeeping requirements of the rule; and a description of the steps taken to minimize any significant economic impact on small entities.

Conclusion

Based on the foregoing, Advocacy suggests that the FSIS postpone the effective date of the rule and reopen the public comment period so that information on potential small business impacts can be obtained. Advocacy would also suggest that the FSIS make a reasonable effort to obtain information as to any potential impact that this rule may have on small entities separate and apart from any public comments received on the issue.

Thank you for your attention to the above matters. If you have any additional questions regarding Advocacy's position on these issues, please do not hesitate to contact Linwood Rayford, of my staff at (202) 401-6880.

Sincerely yours,

Susan M. Walthall
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Office of Advocacy

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