



OFFICE OF CHIEF COUNSEL FOR ADVOCACY

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U.S. SMALL BUSINESS ADMINISTRATION RECEIVED
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FEB 19 1999

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102
300 12th Street, SW
Washington, DC 20250-3700

97768N

Re: New "Policy Statement" on Beef and E. coli 0157:H7, and Its Impact on Small Entities (Date Issued: January 19, 1999).

Dear Sir/Madam:

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 businesses in federal policy making activities.¹ The Chief Counsel participates in rulemakings and other agency actions when he deems it necessary to ensure proper representation of small business interests. In addition to these responsibilities, the Chief Counsel monitors agencies' compliance with the Regulatory Flexibility Act (RFA),² and works with federal agencies to ensure that their rulemakings demonstrate an analysis of the impact that their decisions will have on small businesses.

On January 19, 1999, the Food Safety and Inspection Service (FSIS) issued a sweeping policy change to "clarify" which raw beef products are to be considered adulterated when they contain E. coli 0157:H7. Under the new policy, the definition of an "adulterated" beef product has been expanded to include beef trimmings and other beef products that are tenderized and cubed. Prior to the policy change, only ground beef containing E. coli 0157:H7 was considered adulterated under the agency's regulations.³ Adulterated products are required to be processed further (i.e., cooked) to kill the microorganism, or destroyed.

According to industry experts, beef trimmings and products that are tenderized and cubed constitute a large portion of the beef processing industry. Moreover, ground beef has been the only beef product to be deemed adulterated for the last four years. Therefore, contrary to FSIS' assessment that the foregoing changes represent a mere "clarification"

¹ Pub. L. No. 94-305 (codified as amended at 15 U.S.C. §§ 634a-g, 637).

² Pub. L. No. 96-354, 94 Stat. 1164 (1980) (to be codified as amended at 5 U.S.C. §§ 601-612).

³ In 1994, FSIS took the unusual step of defining raw ground beef contaminated with E. coli 0157:H7 as an adulterated product and unfit for human consumption. According to the January 19, 1999 policy statement, "This was the first time the presence of bacteria in a raw meat product was defined as an adulterant." The Office of Advocacy is not aware of any other instance where bacteria (that is arguably part of the normal biology of raw products) was defined as an adulterant.



or general statement of policy, the Office of Advocacy opines that the changes affect the substantive rights and obligations of a large number of the regulated entities. As such, the changes are subject to the notice and comment requirements of the Administrative Procedure Act (APA).⁴ A number of court decisions make it perfectly clear that agencies may not bypass notice and comment merely by labeling a significant policy change as a clarification.

In Brown Express, Inc. v. U.S., 607 F.2d 695 (5th Cir. 1979), the Notice of Elimination issued by the Interstate Commerce Commission (ICC) was deemed not to fall within any of the notice and comment exemptions of the APA. In that case, the ICC issued a Notice of Elimination stating that it was no longer necessary to notify competing carriers when another motor carrier files an application of an Emergency Temporary Authority (ETA). The ICC determined that notice and comment was not required because, among other things, the change only constituted a general statement of agency policy and that the change would have little substantive or adverse effect on interested parties.

The court in Brown Express stated that the Notice of Elimination was not a simple clarification of a pre-existing policy, “Rather, it effects a change in the method used by the Commission in granting substantive rights. As such, it is a new rule . . .” Id. at 700. The court also explained that the change was not a general statement of Commission policy because such statements only “[announce] motivating factors the agency will consider, or tentative goals toward which it will aim, in determining the resolution of a substantive question of regulation An announcement stating a change in the method by which an agency will grant substantive rights is not a ‘general statement of policy.’” Id. at 701. The 5th Circuit made the additional point that, “[w]hether something is substantive or procedural hinges on the policies underlying the act to which they relate . . . [and whether the rules] depart from existing practice” Id. at 701-702.

The fundamental purpose of notice and comment and informal rulemaking is to allow an agency to gather valuable information from the public and other interested parties regarding the potential impact of the agency’s regulatory decisions and actions. Without public input, an agency runs the risk of causing unanticipated economic harm to affected entities—particularly small entities. Without informal rulemaking, the agency removes itself from the requirements of the Regulatory Flexibility Act and other laws designed to encourage agencies to consider the impact of their regulations on small entities.

The impact of this “clarification” will be to place a substantial new part of the beef industry under the umbrella of those products required to be destroyed or further processed. That umbrella already includes about 40% of the beef supply (represented by ground beef). The agency needs to issue a proposed rulemaking and address several important questions: What percentage of the industry will be impacted by the policy change? What percentage of those impacted are small businesses? What alternatives exist that are less burdensome? What are the costs and benefits of the proposed change? Is this policy change necessary? How successful/useful is the current process of

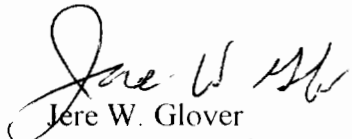
⁴ 5 U.S.C. § 553.

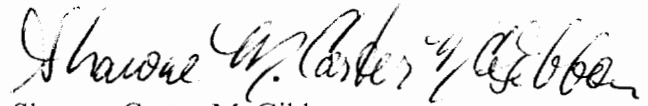
sampling to identify E. coli, and should it be expanded? These and other significant questions may never be answered without the benefit of notice and comment rulemaking.

The industry is already under enormous pressure to implement the Hazard Analysis and Critical Control Point (HACCP) regulations.⁵ This "clarification" amounts to a heaping on of regulations. Moreover, inadequate attention has been given to measures that would eliminate E. coli 0157-H7 from the beef supply (i.e., irradiation or similar technologies). Expanding the definition of adulteration does nothing to advance the ultimate goal of eliminating pathogens from the beef supply. Similarly, expanding the definition does little to improve the questionable benefits of sampling as a mechanism for prevention.

The Office of Advocacy urges FSIS to suspend immediately its January 19, 1999 policy statement that incorporates beef trimmings and other beef portions in the definition of adulterated beef products until the public has a meaningful opportunity to comment. To do otherwise might cause the agency to run afoul the APA and established case law. Please do not hesitate to contact our office if you have any questions, 202-205-6533.

Sincerely,


Jere W. Glover
Chief Counsel for Advocacy


Shawne Carter McGibbon
Asst. Chief Counsel for Advocacy

⁵ The Office of Advocacy commissioned a study on the impact of HACCP and other regulations on small businesses. The study, *Impacts of Federal Regulations, Paperwork, and Tax Requirements on Small Business* (February 1999), concluded that small businesses subject to HACCP regulations suffered a disproportionately high economic impact when compared to their large counterparts. In the category of poultry slaughterers, for instance, the regulations cost 2.95% of their annual revenue. Of course, that amount would likely increase dramatically if presented as a percentage of profits instead of revenue. Also, poultry slaughterers pay 15.31 times the amount to comply with the regulations in relation to their large counterparts. The significant impacts and disproportionately high costs for small firms remained even though some regulatory flexibility measures were included in the regulations. The report also details information for cattle/hog slaughterers and raw ground processing plants. Please note the attached chart that was excerpted and reproduced from the report. Copies of the report are available on our web site: www.sba.gov/advo.

**IMPACTS OF FEDERAL REGULATIONS,
PAPERWORK, AND TAX REQUIREMENTS
ON SMALL BUSINESS**

**Report Prepared for the
OFFICE OF ADVOCACY
U.S. SMALL BUSINESS ADMINISTRATION**

by

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**HENRY B. R. BEALE, PRINCIPAL INVESTIGATOR
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February 1999

**EXHIBIT VI-3:
ECONOMIES OF SCALE AND SIGNIFICANCE OF IMPACTS ON SMALL FIRMS
(Continued)**

Agency/Regulation/Industry	Cost as a Percent of Revenue	Average Unit Regulatory Cost Index	Regulatory Flexibility Measures
<u>EPA</u>			
Underground Petroleum Storage Tanks Financial Responsibility			
Retail Motor Fuel	N.A.	4.47	Options
General Industry	N.A.	36.50	Options
Local General Government	N.A.	19.28	Options
Drinking Water: Lead & Copper Public Water Systems	N.A.	24.09	Several
<u>USDA</u>			
Pathogen Reduction & HACCP			
Poultry Slaughter	2.95 %	15.31	Several
Raw Ground Processing	2.08 %	31.19	Several
Cattle/Hog Slaughter	2.04 %	12.74	Several