

Suggestion for Regulatory Reform

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Regulating Agency: USDA
Subagency: FSIS

Citation : 61 Fed. Reg. 38805, July 25,1996

Authority: Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems (RIN: 0583-AB69)

Description of Problem:

This Regulation may be unlawful because of violations of the following Laws:

(1) PL 103-304, which required that the USDA establish an Office of Risk Assessment and Cost Benefit Analysis which shall be under the direction of a Director appointed by the Secretary. It also required that the Secretary Publish in the Federal Register, for each proposed major regulation-----that is promulgated by the Department after October 13, 1994, an analysis with as much specificity **as** practicable, of--. I could find no evidence that this required analysis was published. However, an internal use only review paper titled "Review of the Pathogen Reduction: Hazard Analysis and Critical Control Point Systems Regulation dated April **4**, 1996 was issued by ORACBA and submitted to Keith Collins, Chief Economist, USDA for distribution at his direction. I obtained a copy of this report, without submitting a FIOA request., with a cover letter dated September 6,1996 and also a copy of **an** unsigned and undated copy of a response to the report provided by FSIS. Perhaps there is a copy of this report in the OIRA file on this regulation and perhaps a copy was placed in the USDA Docket #93-016F file sometime after the Rule was published on July 25, 1996, along with over 6800 public comments. The GAO file OGC-96-31, which is the report number on the GAO report to Congress required by section 801(a)(2)(A) of title **5**, USC, did not contain a copy of this report on July **29**, 1996.

(2) The Congressional Rulemaking Report for RIN 0583-AB69, the HACCP Rule, submitted to GAO did not comply with the requirements of the Congressional Review Act. This Rule **was** one of the early Rules processed by GAO under this ACT and reports GAO/T-OGC-97-29 and GAO/GGD-102R report many problems with agency compliance with this ACT. I have in my files the documents to support the above claim. In fact, the only information supplied to the GAO or Congress on the HACCP Rule was a copy of the Rule. The GAO report OGC-96-31 **was** prepared solely on information in the Rule which did not contain references to the many GAO reports or the SBA Office of Advocacy letters that contain material information.

(3) USC 28.535(b) states" Any information, allegation, or complaint received in a department or agency of the executive branch of Government relating to violations of title 18

involving Government officers and employees shall be expeditiously reported to the Attorney General by the head of the department or agency, unless---. When I found out that USDA was ignoring the comments of the SBA Office of Advocacy, was making false claims regarding the safety of meat and poultry and was also ignoring the sciences of Quality Control and Risk Analysis, I submitted a letter of comment to the Docket Clerk in which I alleged fraud in the rulemaking process and reminded the Secretary of his duty under USC 28.535(b). Copies of my letter dated November 8, 1995 were sent to J.W. Glover, SBA, Vice President Albert Gore, Attn. Elaine Kamark, NPR, and Office of Management & Budget, Attn. Sally Katzen. Furthermore, I verified that a copy of my letter was in the OMB file at the time the Final Rule was evaluated by OMB. I also filed a GAO FraudNet complaint on September 13, 1996 when it became obvious that this Rule was not going to be processed in Congress under the Congressional Review Act. The FraudNet case number is 38735. This case was processed as a normal fraud case and was sent to the USDA Inspector General for investigation. The lack of information in the Notes of Decisions listed in Westlaw makes me wonder if Agency Heads pay any attention to this law.

The letter from J.W. Glover, Chief Counsel for Advocacy to Diane More, Docket Clerk for the HACCP Rule, dated July 5, 1995 states: "It is a basic principle of administrative law that the failure to follow proper procedure invalidates a regulation, *Batterton v. Marshall*, 648 F.2d 694, 711 (D.C. Cir. 1980)". Also the notes listed in the case of *St. James Hospital v. Heckler*, 760 F.2d, 1460 decided April 18, 1985 appear applicable when evaluating the validity of the HACCP Rule. 1. Administrative Law and Procedures, It is agency's duty to establish statistical validity of evidence before it prior to reaching conclusions based upon that evidence, not public's duty to inform agency of statistical invalidities in its evidence. 6. Administrative Law and Procedure, Opportunity under Administrative Procedures Act to comment on proposed rules is meaningless unless agency responds to significant points raised by public. 5 U.S.C.A. para. 553(c). If the HACCP Rule has been a nullity from the start, will anyone damaged by the enforcement of the Rule have a claim against the taxpayers under the Tort Claims Act?

Another very significant problem with the HACCP Rule and the entire FSIS program is its very large cost. According to USDA press release number 0104.02, 4/16/2002 the USDA's budget request to fund the FSIS program in FY2003 is \$905 million. If I use the OIRA rule of thumb that the indirect cost of a regulation is 100 times the direct cost, this means that the FSIS program costs about \$90 billion a year. Past costs have been much smaller but there are many GAO reports that have pointed out how cost ineffective the FSIS program has been for many years. There is little if any reliable evidence that this or any other inspection or statistically based effort has reduced the number of illnesses or deaths caused by pathogens in meat or poultry. The recent HHS, USDA and GAO reports on this subject disagree greatly but they are all supposedly based on CDC data. People who editorialize on the CDC information are apparently unable to recognize the difference between estimates (guesses) and facts. Given a large enough data base one can usually find some type of statistical manipulation that will tend to support any conclusion desired by the manipulator.

The HACCP Rule has been especially hard on small businesses. Even the recall of one day's production can and has caused businesses to fail. However, I have not seen a single report of

a recall actually preventing a serious illness or death, nor have I seen any analysis would lead one to expect the probability to be significantly different. In fact, examination of the data and analysis presented in the article titled "Topics in Microbial Risk Assessment: Dynamic Flow Tree Process published in Risk Analysis, Vol. 18, No. 3, June 1998 suggests that the HACCP quality control procedure is not applicable to pathogens in raw meat. The article "The Role of Variation, Mistakes, and Complexity in Producing Non Conformities", Journal of Quality Technology, Vol.27, No,3, July 1995 is of interest in this regard. Scientists working in the field of statistical quality control have years of experience in trying to reduce mistakes by humans in all types of processes, yet FSIS has apparently neglected to bring these people into the HACCP process.

Proposed Solution:

It seems unlikely that a significant reduction in foodborne illnesses from pathogens in meat and poultry can be obtained by a HACCP System. Visual inspection has conclusively been shown to be useless. Pathogens are a fact of nature and like other natural hazards such as fire, lightning and tornadoes are probably with us for ever. However, the consumer has the ability to protect himself from pathogens in food that is cooked at the consumption site. The obvious way to save billions each year is to let the state sanitation inspection system handle meat and poultry processing plants as an extension of the sanitation inspection programs for restaurants, grocery stores and Custom Meat Processing plants that are exempt from Federal Inspection. A few million dollars a year spent to educate consumers about food safety risks and prevention measures would likely be cost effective. USDA made the same mistakes of initiating a public education program on listeriosis and plant processing changes at the same time. The results are published in an article "Reduction in the incidence of Human Listeriosis in the United States" JAMA, Vol.273, No.14. The FoodNet system can not possibly measure the change in rates caused by HACCP, consumer education, natural effects, etc. However, one could get some idea of the effect of the FSIS program by removing it and seeing the results.

Estimates of Economic Impacts: This would be a useless guessing game so sensitive to many assumptions that I would not care to make a guess.

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