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Department of Animal and Dairy Sciences Box 9815 Mississippi State, Mississippi 39762 Phone (601) 325-2802 Fax (601) 325-8873

February 24, 1999

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

Re: Docket No. 97-068N: Beef Products Contaminated with Escherica Coli 0157:H7

To Whom It May Concern:

I am writing in reference to the above named docket number that was published in the Federal Register of January 19, 1999 (Volume 64, Number 11, pages 2803-2805). Since we now operate under the mandate that ground beef which tests positive for *E. coli* 0157:H7 is considered to be adulterated and to be used for human food must be properly processed (cooked) in order to destroy this organism, I can see where the proposal to include all non-intact beef cuts into this same category is justified. This is true because if the organisms were present on the surface they could well be introduced to the interior of the cuts by processes such as injecting, cubing, marinating, etc. and these cuts of beef might be cooked to temperatures that are inadequate to kill the pathogen. The justification not to include intact beef cuts into this category is also justified in that the heat applied to the surface of these cuts upon proper cooking is adequate to kill these organisms if they are present. Also, there is no evidence that these organisms can migrate into the interior of intact beef cuts. However, I am generally opposed to the concept that beef which tests positive for this organism is considered to be adulterated. I will offer specific points on this matter as may be noted below.

The matter of a meat product being considered adulterated if it tests positive for a particular organism is a marked change, until 1994, in the longstanding policy of USDA relative to microbiological testing and one that I do not believe is supported by law. For example, American Public Health Association et al. vs. Earl Butz, Secretary of Agriculture, et al. No 73-1142 United States Court of Appeals, District of Columbia (Argued Jan. 22, 1974 and decided Dec. 19, 1974) clearly stated that adulterated refers to and is directed at poisonous or deleterious additives and filthy, putrid or decomposed substances but not to substances such as salmonella and other bacteria which may be inherent in

meat. This case further states that Congress did not intend that inspected and passed meat would be free of salmonellae, or other microorganisms.

The organism in question is merely a variant of the normal visceral microbial population of warm blooded animals and thus may be inherent in meat and not covered in the intent of the law. Likewise, this same strain of organism may be present in pork, lamb, and poultry but there is no apparent concern about this because these products are generally cooked to a "well-done" degree on doneness. These same organisms are also present in fruits and vegetables and likewise the government does not seem to be concerned with this situation although many of these items are eaten raw. A recent publication from the American Meat Science Association presented some interesting data about the odds of being affected by death or injury to the following situations: lightning 1.29/million; tornadoes 4.07/million; thunderstorms 1.71/million; hail 0.02/million; E. coli 0157:H7 from any source 1.10/million; E. coli 0157:H7 from ground beef 0.074/million. From these data, it appears USDA would be working in a more fruitful field if they eliminated lightning, tornadoes, and thunderstorms instead of worrying about E. coli 0157:H7. However, we don't have much, if any, affect on mother nature and the same may be the case with the E. Coli organism.

Another relevant point to consider is that these organisms, like listeria and other food borne pathogens are much more of a danger to the very young, the very old, those undergoing chemotherapy, and those affected with the HIV virus. A much more effective method of removing the danger to those who are the most likely to be affected is to properly inform the public about proper cooking and personal hygiene practices of all U.S. citizens and immigrants. This is especially true since a negative test for the organism in no way means the organism is not present in the balance of the lot of product tested. It has been reported that due to the low incidence rate of the *E. coli* 0157H:7 organism in beef that it would take 3,000 negative tests per 10,000 lbs of meat to insure that the 10,000 lb lot of meat would be free of *E. coli* 0157:H7. If this is true, or even close to being true, one or two negative tests for *E. coli* 0157:H7 from a days production in a major meat plant could lead the public to think that if all product that is passed for sale by FSIS is safe to eat any way one may choose since it tested negative for *E. coli* 0157:H7.

About 3% of sea gull droppings test positive for E. coli 0157:H7 (21 of 700 samples) while in 1996 FSIS tested 5,326 samples of ground beef and determined that only 4 were positive for this same organism. I fully realize that FSIS has nothing to do with sea gull droppings, but thought the incidence of this organism in nature should be pointed out in relation to its incidence rate in ground beef.

FDA has a publication and a policy about contamination in many foods. The title of this document is "CURRENT LEVELS FOR NATURAL OR UNAVOIDABLE DEFECTS IN FOOD FOR HUMANS THAT PRESENT NO HEALTH HAZARD". This document states that the following natural contaminates are allowed in foods without causing health hazards, but how can they make such a conclusion if the E. coli 0157:H7 organism is a natural one in the environment? Some examples of contamination allowed are: 1) an average of 1 mg of mammalian excreta, "feces from any mammal", per pound of capsicum pods and they are not necessarily cooked before being eaten; 2) cocoa powder may contain up to 4 rodent hairs per sample; 3) Dried eggs may contain up to 100,000,000 bacteria per gram; 4) mace may contain up to 3% insect fragments or 3 mg of feces per lb; 5) apple butter may contain no more than 4 rodent hairs per 100 grams. These are only a few examples of many that are contained in this publication. My point about bringing this information to the surface in this letter is to point out how the Food & Drug Administration regulates the major portion of the food industry with "UNAVOIDABLE FOOD DEFECTS" and I believe that with the wide spread incidence rate of E. coli and E. coli 0157:H7 that this may need to be considered as an "unavoidable defect" of ground beef considering the current unavailability of any approved method to insure the destruction of these organisms and still have raw products.

Although there has been much evidence to show where irradiation could eliminate these organisms USDA has been unwilling to even publish any proposals for the allowance of such technology to eliminate this potential food hazard until just recently, and this was only an announcement that USDA would soon publish such a proposal. Even if all ground beef and non-intact beef cuts are manufactured with the use of irradiation to destroy these organisms, at the point of manufacture, there are no assurances that it will not become recontaminated elsewhere in the food distribution system (transportation, food service, retail, home). There is no way in which USDA, or any other agency, can actually cause the production of a "ZERO RISK" food or foods. In every case of disease caused by this organism from beef, that I am aware of, the illness could have been prevented by the proper cooking of the product.

This is something that must always be done if one wants to remove all the chances of getting ill from eating ground beef or other non-intact cuts of beef as well as with certain other foods such as eggs, poultry products, pork, oysters, etc.

In conclusion, I wish to say that I hope you will give my comments serious consideration because the present approach of testing costs a lot of money and gives consumers a false sense of security that the ground beef or non-intact beef items that are offered for sale are free of *E. coli 0157:H7*, because FSIS requires testing for this organism and will only allow product to be sold that has tested negative for the *E. coli 0157:H7* organism. A better option than testing for *E. coli 0157:H7* might be to require a plainly visible statement on the label of all of these types of products that they need to be cooked to an internal temperature of at least 150 degrees F, thereby giving the end-user (consumers, food service establishments, school cafeterias, etc.) the information needed to prepare and serve these products in a safe manner.

Sincerely,

Robert W. Rogers, Ph. D., PAS, Dplm. ACAFS
Professor of Animal & Dairy Sciences
and Food Science and Technology, and
Member of the Regulatory Affairs Committee of the American Meat Science Association