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AQIS
AUSTRALIAN QUARANTINE AND INSPECTION SERVICE
Department of AGRICULTURE, FISHERIES AND FORESTRY - AUSTRALIA

19 April 1999

97-068N
97-068N-77
R. R. Biddle

FSIS Docket Clerk
(Docket No 97-068H)
Food Safety Inspection Service
US Department of Agriculture
Room 103 Cotton Annex
300 12th Street, SW
WASHINGTON DC 20250-3700
United States of America

Dear Sir/Madam

BEEF PRODUCTS CONTAMINATED WITH ESCHERICHIA COLI 0157:H7

The Australian Quarantine and Inspection Service has considered the notification given by the "Federal Register", Vol 64, No 11 of 19 January 1999 (Docket No 97-068N) and desires to provide comments relevant to the Food Safety Inspection Service (FSIS) policies it is proposing to utilise to prevent the distribution of beef products adulterated with *E.coli 0157:H7.*

The Federal Register Notice identifies that a number of types of beef products are of concern and should be deemed adulterated when *E.coli* 0157:H7 is detected because this pathogen may be introduced below the surface of the product, either at the time of its manufacture or because the product may be further transformed prior to distribution in a way which gives rise to this purported risk. It is contended that the final cook step to which adulterated products are subjected may not be adequate to destroy (or reduce to safe level) this pathogen when present below the surface of the beef product. The FSIS indicates it may reconsider its sampling and testing program for *E.coli* 0157:H7, as well as the scope of products deemed adulterated when this pathogen is detected.

Hazard vs risk

The information presented as the rationale for a possible change in regulatory requirements to include a wide range of non-intact beef products is that a hazard (*E.coli* 0157:H7 present in a small proportion of beef products usually at low levels of viable organisms) could pose a risk to human health. It is not rigorously established that the presence of this hazard in or on the types of non-intact beef products cited is causing cases of human illness. This is a distinct difference to the case of ground beef, where such a link has been established. Therefore any extension of testing to products other

than ground beef is likely to represent a waste of regulatory resources as non-intact, fresh beef products, other than ground beef, have not to date been implicated as food vehicles causing human illness with *E.coli* 0157:H7.

In this regard it is noted that the FSIS does not sample a large range of non-beef and poultry products for *E.coli* 0157:H7 because a link between these products and human illness has not been established. This prudent approach should continue to be applied to non-intact beef products, other than ground beef.

Limitations of end-product pathogen testing

In considering any change of *E.coli* 0157:H7 testing requirements to include a wide range of non-intact beef products, FSIS should consider the many limitations of end-product testing programs as applied to fresh meat (and other perishable foods). Enteric pathogens, including *E.coli* 0157:H7, are typically present in low numbers on a small percentage of dressed carcases (and derived cuts). The pathogens of concern are non-uniformly distributed and therefore, unless large numbers of samples are taken and sensitive testing methodology is employed, their presence is unlikely to be detected. For example, if *E.coli* 0157:H7 occurs in ground beef at a prevalence of 0.1% it can be shown mathematically that there exists a 90% probability that 100 tests applied to a product batch will be negative (ie a batch containing the pathogen will be falsely passed). Expressed in another way, and assuming a 0.1% defect level, approximately 3000 samples need to be taken to ensure a 95% probability that a batch of product does not contain *E.coli* 0157:H7. Such sampling levels are clearly untenable.

In general, pathogen testing when applied to raw meat products is likely to falsely clear product batches and gives rise to consumer complacency in the area of proper handling and cooking of fresh meat. For these and related reasons the International Commission on Microbiological Specifications for Foods (ICMSF) does not recommend end product testing approaches for pathogens in fresh meat. Both ICMSF and the Codex Alimentarius Commission recommend the use of properly validated and verified Hazard Analysis Critical Control Point (HACCP) procedures in the production of fresh meat, coupled with available interventions throughout the production continuum to limit the pathogen load. This should be coupled with appropriate consumer education in safe meat handling and cooking procedures.

Under these circumstances it would be valid for FSIS to microbiologically monitor the fresh meat supply to establish that pathogen reduction targets are being achieved through the operation of HACCP and associated measures. This approach would avoid the significant practical limitations of end-product testing programs.

Meat exporting country impacts

Were FSIS to decide that *E.coli* 0157:H7 testing be extended to non-intact cuts and manufacturing meats, particular practical difficulties (depending on the nature of the FSIS requirements) could be posed for meat exporting countries such as Australia.

If testing were required of product prior to shipment to the US, then production runs would need to be identified, sampled and cleared at an early stage. This would remove the flexibility of industry to select product from cold storage inventory for shipment to the US. A further difficulty relates to beef cuts. This is because their ultimate fate in the US market (eg for use in making reformed steaks) is not known at the time of making shipments.

If testing were to be performed at port of entry inspection, considerable delays and associated costs could adversely impact on the established trade. Again the problem of not knowing the ultimate fate of cuts could arise. Therefore, the impact of any testing measures on exporting countries would need to be carefully considered in respect of any rule making in this area.

Pathogens other than *E.coli* 0157:H7

A range of enteric pathogens capable of causing human illness may be present in or on raw meat and poultry products. Some of these pathogens (eg *Salmonella* and *Campylobacter*) may be a greater cause of meat-borne human illness, both in terms of morbidity and mortality. Other enter-haemorrhagic strains of *E.coli* may be meat-borne and also constitute a risk to human health. The proposal for specific testing programs for *E.coli* 0157:H7 in certain types of beef products may therefore not be consistent in risk management terms. If similar or greater microbial risk levels are able to be managed in other meat and poultry types through the application of HACCP principles, then the differential treatment accorded some beef products in respect of the single pathogen *E.coli* 0157:H7 should be carefully considered. This consideration should extend to the relevant provisions of the World Trade Organisation in relation to sanitary measures impacting on trade.

As indicated above properly applied HACCP measures, supported by appropriate microbiological validation and verification procedures, enjoy international acceptance and obviate the need for end-product microbiological testing requirements for fresh meat.

I thank you for the opportunity to present the foregoing comments in response to this Federal Register notification.

Yours sincerely

R R Biddle
Assistant Director
Food Policy Branch

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

MAR 22 1999

Mr. Robert Biddle, Assistant Director
Food Policy Branch
Edmond Burton Building
Baton ACT, GPO Box 858
Canberra ACT 2601
Australia

Dear Mr. Biddle:

In October 1994, in response to an outbreak of foodborne illness that resulted in several deaths from the consumption of undercooked ground beef contaminated with *Escherichia coli (E.coli)* O157:H7, FSIS declared *E. coli* O157:H7 to be an adulterant in raw ground beef and began a sampling program to test for *E. coli* O157:H7 in raw ground beef prepared in federally inspected plants and in retail stores.

However, the public health risk presented by raw beef products contaminated with *E. coli* O157:H7 is not limited to just raw ground beef products. To better ensure the safety of the United States' food supply, on January 19, 1999, FSIS published a Federal Register notice clarifying its policy regarding raw beef products contaminated with the *E. coli* O157:H7 pathogen. FSIS has determined that additional raw beef products contaminated with *E. coli* O157:H7 will be considered adulterated unless they are further processed to destroy the pathogen. FSIS relied heavily upon the deliberations of the National Advisory Committee on Microbiological Criteria for Foods for guidance regarding the public health risk presented by raw beef products.

FSIS has determined that raw beef that has been injected with solutions, mechanically tenderized, chopped, ground or minced (referred to as "non-intact" beef) is adulterated if it is contaminated with *E. coli* 0157:H7, unless the product is cooked or further processed in some other way that will destroy pathogens. Beef trimmings are also considered adulterated if they will be processed into "non-intact" products and contain *E. coli* 0157:H7, unless they are cooked or further processed to destroy pathogens.

No response is required to this letter. However, FSIS is requesting comments from all interested parties regarding the issues raised in the enclosed Federal Register notice. An FSIS Backgrounder that explains the new policy is also enclosed. Comments should be sent to the address specified in the Federal Register notice. FSIS looks forward to receiving comments on its new policy from its trading partners.

If you need more information or have any questions, please contact me at 202-720-6400. My fax number is 202-720-7990.

Sincerely,

Mark Manis, Director
International Policy Division
Office of Policy, Program Development
and Evaluation

Enclosures

cc:
Randy Zinter, Minister Counselor, American Embassy, Canberra
Peter Miller, Veterinary Counselor, Embassy of Australia