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00-022N
00-022N-5
Ann McDonald

Dear Sir/Madam

RE: FEDERAL REGISTER NOTICE (DOCKET NO 00-022N): E. COLI O157:H7 CONTAMINATION OF BEEF PRODUCTS

We welcome the opportunity to comment on the FSIS draft notice '*E. coli* O157:H7 Contamination of Beef Products' [Docket number 00-022N] and on the guidance document referred to in the Notice. These comments were prepared by a working group consisting of Australian Quarantine and Inspection Service (AQIS), Commonwealth Scientific and Industrial Research Organisation (CSIRO), and Meat and Livestock Australia.

Our main points are listed below:

1. Australia shares FSIS' desire to reduce the risk of food borne illness attributed to meat and meat products.
2. Existing food safety programs which include, and place emphasis on, good manufacturing practices, standard sanitation operation procedures and HACCP, result in the preparation of meat of an excellent microbiological status.
3. The meaning of "reasonably likely to occur" is unclear.
4. The FSIS policy and Federal Register Notice are premised on the existence of satisfactory interventions for the control of *E. coli* O157:H7 to levels not able to be detected by the FSIS method or its equivalent. Food safety regulations will only be effective where technology exists that will permit compliance. Australia is concerned that the interventions, with the exception of bactericidal procedures (cooking and irradiation) are not adequately validated for the elimination or control of *E. coli* O157:H7.
5. A critical component of any reassessment is the desired outcome (in this case not detectable by the FSIS method) and how performance against the desired outcome can be measured. Key to this is the methodology used for testing of product for *E. coli* O157.H7. This methodology should include sampling plans (numbers, frequency, size etc) as well as performance criteria for both the test method and the sampling plan.
6. A clear science-based policy needs to be developed for the validation of CCPs for pathogens, especially those that occur with a low frequency at the control point being tested. Australia considers that it is premature to utilise interventions as CCPs as research to date does not provide a clear indication of their efficacy.

Australia believes that although the desired outcome of a reduction or elimination of *E. coli* O157:H7 and other pathogens in non-intact beef products is commendable, a similar outcome could be achieved by changing the policy from a requirement for *E. coli* O157:H7 levels to be not detected to one that specifies achievable performance criteria predicated on a scientifically-based sampling and testing program.
Australia intends making a submission demonstrating that Australia's HACCP-based MSQA program provides a food safety outcome that is equivalent to that specified in the Federal Register Notice.

Yours faithfully

Ann McDonald
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December 2002

COMMENTS ON FSIS FEDERAL REGISTER NOTICE 'E. COLI O157:H7 CONTAMINATION OF BEEF PRODUCTS' (DOCKET NUMBER 00-022N)

Summary

1. Australia shares FSIS' desire to reduce the risk of food borne illness attributed to meat and meat products.
2. Existing food safety programs, which include, and place emphasis on, good manufacturing practices, standard sanitation operation procedures and HACCP, result in the preparation of meat of an excellent microbiological status.
3. The meaning of "reasonably likely to occur" is unclear.
4. The FSIS policy and Federal Register Notice are premised on the existence of satisfactory interventions for the control of *E. coli* O157:H7 to levels not able to be detected by the FSIS method or its equivalent. Food safety regulations will only be effective where technology exists that will permit compliance. Australia is concerned that the interventions, with the exception of bactericidal procedures (cooking and irradiation) are not adequately validated for the elimination or control of *E. coli* O157:H7.
5. A critical component of any reassessment is the desired outcome (in this case not detectable by the FSIS method) and how performance against the desired outcome can be measured. Key to this is the methodology used for testing of product for *E. coli* O157:H7. This methodology should include sampling plans (numbers, frequency, size etc) as well as performance criteria for both the test method and the sampling plan.
6. A clear science-based policy needs to be developed for the validation of CCPs for pathogens, especially those that occur with a low frequency at the control point being tested. Australia considers that it is premature to utilise interventions as CCPs as research to date does not provide a clear indication of their efficacy.

General

The objective of the notice in protecting public health and reducing the risk of food-borne illness attributable to meat and meat products is a sound one which enjoys support of consumers, the meat industry and regulatory authorities.

Measures to ensure the safety of meat and meat products should be based on: a risk management approach, sound science, integration of control measures at all stages of the production chain from farm to consumer, cost effectiveness and a need to ensure interventions are practical in terms of day to day industry operations. These criteria were identified by the World Congress on Meat and Poultry Inspection held in Texas in 1993 and are reflected by the general principles enunciated by the Joint WHO / FAO Codex Alimentarius Committee on Meat Hygiene Hygiene (Proposed general principles of meat hygiene CX/MPH 03/03 October 2002).

A further important consideration is that the notice will impact upon countries such as Australia that are significant suppliers of meat to the United States. Australia will be required to comply with the additional measures specified in the document. Under this circumstance the impact of additional measures should be such as to not compromise the rights of contracting parties to the World Trade Organisation (WTO), including the provisions of the Sanitary and Phyto-sanitary (SPS) agreement. It is relevant to note that the SPS agreement specifically provides for the acceptance of 'equivalent' measures.

Our comments are made using specific headings that were used in the Federal Register Notice, hereafter referred to as the Notice. Many of the comments from Australia are common to the various parts of the Federal Register Notice and associated guidance documents.

HACCP

It is now accepted (Brown et al, 2000; Altekruse et al, 1998; Bovee et al, 1997; van Schothorst, 1996; Theno, 1995; ICMSF, 1986), and Australia agrees with FSIS, that preventative, HACCP-based measures are the most appropriate and effective method for ensuring food safety. To this end HACCP based food safety programs have been mandatory in the Australian meat industry since 1996. Three elements of these programs:

- Good Manufacturing Practices (GMPs),
- Standard Sanitation Operating Procedures (SSOPs); and
- HACCP

are essential and equally significant in controlling the contamination of meat products with *E. coli* O157:H7 in slaughtering and boning establishments. We, therefore, contend that Notice 00-022N is inappropriately focussed on CCPs. The impact that GMPs and SSOPs have on the incidence of *E. coli* O157:H7 and other pathogens on fresh meat products should be acknowledged in the Notice and considered when assessing the adequacy of establishments' food safety programs.

E.Coli O157: H7 Policy

Hygienic dressing procedures, operational requirements and HACCP programs have been designed to control *Salmonella*. Procedures that control *Salmonella* will also control other food-borne pathogens including *E. coli* O157:H7. In this respect we understand that the Notice is not necessarily asking for new control measures to be implemented, only that the control measures are capable of reducing, eliminating or preventing the growth of *E. coli* O157:H7 to undetectable levels.

Although Australia agrees with the desired policy outcome of undetectable levels of *E. coli* O157:H7, we believe that it is impractical from an implementation point of view:

- We are unaware of any interventions that will assure product will not contain viable *E. coli* O157:H7, a view apparently held by the FSIS as the notice suggests that the only bactericidal interventions known to the FSIS are cooking at appropriate temperatures and irradiation under appropriate conditions;
- Interventions provide for reductions in pathogen load but not elimination;
- Testing for *E. coli* O157:H7 to confirm effective elimination is impossible. "Undetectable levels" is defined in the policy as a level that would not be detectable 'using the FSIS testing method or a method with sensitivity at least equivalent to FSIS' method'. The FSIS method applies to ground beef (Directive 10,010.1). FSIS has not provided any direction as to a suitable method for carcasses and trim. This has implications for likely interventions, monitoring and sampling plans as well as the methodology used to detect and confirm *E. coli* O157:H7 in the various beef products.

Relevant Data Requiring Reassessment

FSIS has decided that data from the new testing method and the Smith *et al.* (2001) and Elder *et al.* (2000) studies represent a change that requires establishments to reassess their HACCP plans. While it may be acknowledged that the improved methodology has led to an increase in our knowledge of the prevalence of *E. coli* O157:H7 in live cattle, it is of our opinion that this change has led to a perception of increased risk rather than an actual increase in incidence of *E. coli* O157:H7. The actual level of risk may well be unchanged.

It is suggested that risks might be determined by public health statistics, in this instance the prevalence of disease associated with *E. coli* O157:H7. Performance criteria for *E. coli* O157:H7 could be determined relative to public health goals. The Codex Committee on Food Hygiene has proposed principles for microbiological risk management including guidance on determining the appropriate level of protection (Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management. CX/TH 01/7 October 2002).

Australia questions whether the US data quoted represents a change directly applicable to countries other than the US. Again, the Codex Committee on Food Hygiene has made the following recommendations on considering differences between countries (CX/FH 01/7):

5.1.8 Regional considerations

In the interests of safeguarding human health and minimising the incidence of foodborne diseases, the existence of regional differences in the prevalence of various pathogens in the food chain should be recognised and taken into account in the risk management process. Principles which apply in this regard include the following:

- Risk management should be based on microbiological prevalence data, when available, from the whole food chain and, if appropriate, disease incidence and prevalence data.
- Risk management should take into account the existence of regional differences such as the prevalence of foodborne pathogens in the food chain.

Outcomes of Reassessments Based on Relevant E.Coli O157: H7 Data

The reassessment of HACCP plans requires establishments to determine if *E. coli* O157:H7 is a hazard " reasonably likely to occur". The Notice does not give adequate indication as to how " reasonably likely to occur" might be interpreted. In the interest of natural justice and consistency of application it is desirable that this term should be better defined.

The Notice states that "if this pathogen is a hazard reasonably likely to occur, then it must be addressed in a HACCP plan through one or more CCPs designed to control the pathogen". Thus the notice makes it clear that FSIS considers CCPs as the only way to control the pathogen. However, there is a major weakness in this approach in that there are no known CCPs (except cooking and irradiation) that might be able to achieve the level of control FSIS requires. Australia contends that sanitation programs, good hygienic practices, slaughter techniques and staff training etc are approaches to process control that will have an impact on the incidence of pathogens including *E. coli* O157:H7 in intact meat products and if implemented well can achieve acceptable control of the pathogen.

The Notice indicates that a processor can determine compliance with the Notice 'using the FSIS testing method or a method with sensitivity at least equivalent to FSIS' method'. We assume that this method is that in Chapter 5 of the USDA/FSIS Microbiology Guidebook 3rd edition. The Notice does not specify a test method.

The Notice does not provide guidance on how processors will define a production lot for the purpose of selecting samples for testing purposes. Some directions are given to grinders, but no directions applicable to processors (slaughter establishments). Directions on the definition of a lot are necessary so that processors can make acceptable decisions on the disposition or recall of product found to be positive for *E. coli* O157:H7.

There is no direction concerning a suitable sampling plan to determine that carcase or trim products are reduced 'to an undetectable level' Without guidance on the number of samples to be taken per production lot by processors and the size of the analytical unit, it is not possible to determine the testing programs necessary for a processor to verify that their process is producing product that meets FSIS requirements.

It is acknowledged that FSIS intends to reissue Directive 10,010.1 and that the revision may deal with testing of trimmings and carcases. It is understood that this Directive deals with testing by the Agency for the purpose of verification, not testing by processors to determine compliance with the Notice.

Without adequate definition of a lot, sampling plan, or testing method it is not possible for processors to know whether they are complying with the Notice.

Critical Control Points and Sanitation SOP's and Other Prerequisite Programs
The notice requires that there be "one or more CCPs designed to control the pathogen." The notice comments that "FSIS is not aware of any prerequisite programs that are appropriate for use in slaughter and deboning establishments to address *E. coli* O157:H7." We agree that a CCP in slaughter operations is desirable but do not agree that prerequisite programs (GMPs, SSOPs etc) are inappropriate for control of the organism.

The notice defines the acceptability of establishment controls to prevent, eliminate or reduce *E. coli* O157:H7 as "a level that would not be detectable using the FSIS testing method or a method with sensitivity at least equivalent to FSIS' method."
This is, in effect, a microbiological criterion. The Codex Alimentarius document 'Principles for the Establishment and Application of Microbiological Criteria for Food' defines and describes the components required of a microbiological criterion, including analytical methods, a plan defining the number of field samples, microbiological limits and the number of analytical units that should conform to these limits. In this case the number of field samples and size of the analytical unit have not been provided.

Australia has concerns with regard to the use of CCP validation and HACCP verification based on the test results for a specific pathogen that occurs at a low incidence and primarily reflects the highly variable in-coming live animal infection/carrier rate. Given the low incidence of the pathogen and the statistical nature of sampling and testing processes, this is not considered an appropriate monitoring approach. A more suitable criterion for a CCP would be a validated level of in-plant reduction of an approved surrogate for *E. coli* O157:H7.

It is accepted that CCPs are a useful approach to reduce, eliminate, or prevent contamination of product with *E. coli*. We equally assert that many other (non-CCP) activities in food safety programs assist in achieving the objective of controlling *E. coli* O157:H7. Sanitation programs, good hygienic practices, slaughter techniques and staff training are examples of approaches to process control that will have an impact on the incidence of *E. coli* O157 in intact meat products. Neither the Notice nor the guidance document makes adequate allowance for their importance. Rather they seem to put undue emphasis on identification and validation of CCPs.

FSIS has acknowledged the importance of, and relationship between CCPs and sanitation SOPS, in the Final Rule 'Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems' (Federal Register / Vol. 61, No. 144 / Thursday, July 25, 1996 p. 38834):

> HACCP plans aim at ensuring safety at specific critical control points within specific processes, while Sanitation SOP's typically transcend specific processes. Sanitation SOP's are important tools for meeting existing statutory sanitation responsibilities and preventing direct product contamination or adulteration. As such, it is appropriate that they be developed and implemented in the near-term prior to implementation of HACCP. In a sense, the Sanitation SOP's are a prerequisite for HACCP. It is anticipated that some procedures addressed in an establishment's Sanitation SOP's might eventually be incorporated into an establishment's HACCP plan.

In the Guidance document on Beef Slaughter (Guidance for Minimizing the Risk of *Escherichia coli* O157:H7 and Salmonella in Beef Slaughter Operations, FSIS, September, 2002), FSIS has provided considerable guidance on control including design of facilities, airflow, procedures for head removal, dehiding etc. Many of these activities would be considered good hygienic practice rather than CCPs. The competence of staff that is achieved by training and certified through assessment provide confidence that adherence to good hygienic practices and slaughter activities will have the desired impact on controlling contamination of product. In our experience these have been shown to adequately ensure food safety.

The validation of CCPs can only be successful if the objective in eliminating, preventing or reducing *E. coli* O157:H7 is quantified through the use of microbiological criteria, performance standards or some similar measure. Our comments on the lack of microbiological criteria and sampling plans are applicable to the question of how to determine that a process is validated.

The Notice remarks on the use of surrogate organisms in validation. We have made comment on this subject later in the document where we comment on the text of the Guidance Documents.

Interventions as CCPs

The Notice states that there are effective decontamination methods that can be used for preventing, eliminating or reducing *E. coli* O157:H7 and establishments can validate their CCPs for *E. coli* O157:H7 by ensuring that the operation of the CCP in their plant can meet the parameters of the published studies. We question whether there are, in fact, decontamination interventions that can be regarded as CCPs at this time, as we elaborate later (See Attachment 1). We are concerned that once control steps are designated as CCPs, any non-compliance with the one CCP automatically requires stoppage of the slaughter line.

Verification

The notice states that establishment verification activities should include testing for *E. coli* O157:H7 but does not specify details of the test or the sampling plan.

We reiterate that end product testing for a pathogen occurring at low incidence is not an appropriate criterion (AMSA, 1999).

FSIS Directive 10,010.1

Critical to any HACCP program is the measurement of performance against the desired outcome. In the case of *E. coli* O157:H7 FSIS policy is that the levels, if present, not be detected when tested using the FSIS method or an equivalent. However, in the case of a pathogen that occurs sporadically and has low rates of detection in testing programs, the probability of detecting the pathogen when it is present in a single test is very low. Indeed the probability of detection only rises to levels that provide significant confidence when the number of samples tested is large.

This has implications for both testing of establishments for verification of the HACCP plan and CCPs as well as for grinding establishments that have purchase specifications.

Directive 10,010.1 relates to ground beef. As the test performance and sampling plans may be product specific (carcass vs trim vs ground beef) Australia suggests that the Directive be developed to include instructions for intact beef (carcasses and trim)

Attachment 1

COMMENTS ON FSIS GUIDANCE DOCUMENT 'GUIDANCE FOR MINIMIZING THE RISK OF ESCHERICHIA COLI O157:H7 AND SALMONELLA IN BEEF SLAUGHTER OPERATIONS'

INTERVENTIONS AS CCPS

Pre-slaughter interventions

Lot-fed cattle, particularly British breeds such as Angus, frequently are visibly dirtier at slaughter than Bos indicus breeds. Animals transported over long distances are likely to be dirtier than animals transported over short distances (Davies et al, 2000). However there does not appear to be a consistent association between visible dirt or tags (dags) on hides and bacterial contamination of carcases. Vanderlinde et al (1996) showed that there was no correlation between carcase contamination and visible dirt on the hides of cattle. For one high speed line in Canada (285 carcases per hour), van Donkersgoed et al (1997) found that there was a negative association/correlation? between the amount of dirt and tag on the hide and counts of aerobic bacteria, coliforms, and *E. coli*. Counts were lower when tag was shaved off the hides or when the line speed was slowed, but the reductions in counts were less than 0.5 $\log_{10}$ units per cm^2. At a Canadian abattoir that processed 135 carcases per hour, there was weak association only. Kain et al (2001) found that for dairy cattle carcases hide cleanliness and faecal matter consistency were not indicators for cattle likely to produce contaminated carcases. McEvoy et al (2000) found that the introduction of improved hygienic practices during dehiding of dirty carcases reduced TVC at the brisket but in general hide cleanliness had little influence on TVC of carcases.

However, there is little if any evidence of the benefit of washing. In a trial on Bos indicus cattle in SE Queensland, Eustace and Vogler (1998) found that washing slightly increased total counts and had no effect on the prevalence of detection of coliforms or *E. coli*. They also found in an export abattoir that the effect of shearing of cutting lines before cattle were dressed had minimal effect ($p>0.05$) on the average total count on the dressed carcases and on the numbers of carcase samples on which coliforms or *E. coli* were detected.

US research on a chemical dehairing process has shown that it reduces visible contamination but the effect on bacterial load is variable – no effect on the carcase total counts coliforms and *E. coli* in one study (Schnell *et al* 1995) and significant reductions in APC, coliforms and *E. coli* in another with artificially contaminated cattle hides (Castillo *et al* 1998).

We are aware that proprietary chemical treatments (eg. Agwash) have been trialled in laboratory trials. However there is no information available about their effectiveness in a commercial situation. They are not approved for use in Australia, USA or other countries to which Australian beef is exported.

In summary, there is little prospect of pre-slaughter interventions being validated as CCPs.

POST SLAUGHTER INTERVENTIONS

Trimming

The efficacy of trimming in reducing the microbial contamination on carcases is questionable. Laboratory studies have often reported large reductions but these have been obtained under controlled conditions using visible contamination and do not provide a realistic evaluation of the effectiveness of these processes in a commercial environment. Few studies have been conducted using naturally contaminated carcases. Gill et al (1996), studying the effects of trimming and washing on the microbiological characteristics of beef carcasses, observed that trimming appears to

have little effect or may have even resulted in slight increases in bacterial numbers at the sites observed. These findings were also supported by Vanderlinde et al (1996) where at three Australian abattoirs the effect of trimming and washing resulted in an increase in numbers of *E. coli* on beef carcasses and a corresponding increase in prevalence. Trimming is considered to have little effect in Australia on bacterial numbers i.e. 0 to 0.3 log increase. American studies have reported rather greater reductions from trimming. For example, Kochevar et al (1997) reported that knife trimming reduced aerobic plate counts and total coliforms counts by at least 1.4 and 1.6 log respectively. Based on these variable findings, we believe that it is inappropriate to nominate trimming as a CCP.

Steam vacuum systems

These systems are used in Australia for removal of wool fibres and wool dust from sheep carcases but they are little used intervention for beef sides. AQIS Meat Notice 98/1 states that the unit must be used for localised 'spot' treatment only and should be applied to a particular area of carcase surface for a five second contact time.

The studies of steam vacuuming by Dorsa et al (1997a) and Phebus et al (1997) were pilot studies. They were not extended to investigations of sides on a slaughter floor.

In a study involving two steam vacuuming units and five processing plants, Kochevar et al (1997) found that steam vacuuming reduced TPC and total coliform counts (TCC) on carcase surfaces soiled with visible contamination by 1.7 to 2.1 $\log_{10}$ CFU/cm^2. However, for surfaces that had no visible faecal contamination, the reductions in TCC were only around 0.3 $\log_{10}$.

The model studies that are cited in the Guideline Document have focused on removing gross faecal contamination and on the efficacy with which intervention treatments reduce numbers of *E. coli* O157:H7 and other target pathogens. They have limited relevance when considering a whole side in the normal commercial situation where faecal contamination is infrequent. When used for spot treatment as directed, there would be opportunity to treat only approximately 100 cm^2 per side. Therefore for plants where good manufacturing practice is followed and visible faecal material on dressed sides is infrequent, steam vacuuming would be minimally effective as an intervention.

Water washing systems

Data cited in the Guidance Document from the studies of model systems by Delazari et al (1998) and Hardin et al (1995) indicate that water washing could achieve reductions in *E. coli* O157:H7 (applied in faeces) up to 3.5 $\log_{10}$ units. However in the study of Hardin et al water washing was consistently less effective than trimming and the authors commented that washing with water alone was found to be the least effective treatment used in this study.

Data obtained in a New South Wales abattoir in 1995 from a wash cabinet in which beef sides were washed with warm (40°C) water indicated reductions in numbers of faecal coliforms of as little as 0.1 $\log_{10}$ on surface tissue from the neck region of sides to 0.6 $\log_{10}$ in the mid-back region. In summary, we believe that washing can not be considered a CCP. As indicated in the Guideline Document, hot water washes have shown considerable promise for decontamination of beef sides. Gill et al (1999) estimated that commercial hot water pasteurisation of beef sides reduced numbers of coliforms and *E. coli* by around 2 logs. Recirculation of water is necessary otherwise water consumption is prohibitive. Systems need to be carefully designed with adequate controls.

It is premature, we believe, for processors to identify intervention using hot water as a CCP.

Organic acids

In Australia, the use of lactic or acetic acids as an intervention for beef sides is limited. There are several reasons for this.

1. Within the European Union, meat hygiene regulations do not allow their use. A considerable number of Australian processors export to the EU and cannot use any process other than potable water in their plants.

2. While data collected from commercial efficacy trials in Australia and elsewhere have shown an average 1.5 log10 reduction in total aerobic bacteria, they have not always given encouraging results for *E. coli* and other pathogens. In a 1995 Australian trial using a commercial spray cabinet, reductions using 2.25% lactic acid were found to be dependent on ambient temperature conditions, the solution temperature, and location on the beef side. At 15°C reductions on neck tissue after treatment were 0.5 logs.
3. The potential to corrode equipment, and create an uncomfortable work environment.
4. There is documented evidence of the acid resistance of *E. coli* O157:H7. The efficacy of organic acids as carcase interventions might therefore be reduced.
   Huffman (2002) comments that the use of organic acids must be considered with some degree of caution, in light of recent research indicating that acid adaptation of *E. coli* O157:H7 and other pathogens may occur in dilute decontamination fluids in meat packing plants. Samelis et al (2002) reported that a previously adapted *E. coli* O157:H7 strain survived for extended periods in acid containing waste fluids from meat decontamination. Furthermore, these authors point out that survival may increase when acetic acid rather than lactic acid is used for carcase decontamination.

Steam pasteurisation

Steam pasteurisation has been used in packing plants in the US with apparent variable results. The Guidance Document refers to studies of steam pasteurisation that have been published indicating reductions in numbers of *E. coli* O157:H7 of 3 to 4 log10 units. These appear to be model studies in general rather than commercial ones. Data of Gill and Bryant (1997) indicated that the Frigoscandia pressurised steam process reduced the numbers of coliforms and *E. coli* on beef sides in a commercial beef packing plant by at least 2 logs.

We are aware that these units have been used in several commercial plants. We also understand that getting them to operate reliably is very challenging. There have been reports of reductions less than one log. To our knowledge there have not been in-plant validations against *E. coli* O157:H7. We are aware that they are extremely expensive to install in Australia.

For these reasons we suggest that while plants may consider steam pasteurisation as a decontamination step, they should not consider it as a possible CCP.

Chilling of sides

Chilling of sides is discussed in the Guidance Document, though not as an intervention. There is some evidence that chilling *per se* can be regarded as an intervention. In their discussion of results of steam pasteurisation in a commercial packing plant in Canada, Gill and co-workers (Gill and Bryant,1997; Gill et al,1999) observed that counts of coliforms and *E. coli* declined to a greater extent when numbers were assessed after chilling than immediately after the steam pasteurisation. They commented that the microbiological effects of the pasteurising treatment appeared similar to those of the cooling process on non-pasteurised carcases, as both reduced the log numbers of coliforms and *E. coli* by more than 2 logs. The comment was based on observations on the effect of chilling they made previously (Gill and Bryant, 1997).

Similar observations have been made in Australia where dry air chilling is employed. Chilling appeared to reduce counts of coliforms, *E. coli* or the indicator organism *Klebsiella oxytoca* by up to 1.1, 1.0, and 0.5 logs after warm water washing, hot water decontamination, and organic acid treatments respectively. It is widely accepted that effective chilling involves several factors, particularly air temperature, relative humidity, air speed and carcase spacing. However the values and tolerances for these parameters have yet to be adequately established for chilling to be nominated as an intervention CCP. When they are defined, beef side chilling may well prove to be controllable to the extent that reductions in numbers of *E. coli* and other pathogens occur reliably.

Indicator organisms for in-plant validation of HACCP

The Federal Register document states (p 62329) that establishments can validate their CCPs for *E. coli* O157:H7 by challenge studies using an appropriate surrogate for *E. coli* O157:H7 that could include, but not be limited to *E. coli* and coliforms. It further states that there are no situations in which inspection program personnel will ask that establishments introduce pathogenic or harmful bacteria into the establishments to evaluate the effectiveness of CCPs.

However the Guidance Document provides advice that is at variance with that in the Notice. The fourth paragraph on p 27 says:

"There are some studies on the use of various indicator organisms to determine the effect of intervention methods used to control pathogens in slaughter operations. Unfortunately, studies on the effects of carcass decontamination methods on *E. coli* O157:H7 and on indicator organisms were done separately, so that correlation of the effect on *E. coli* O157:H7 and indicator organisms cannot be established."

It is then stated that "...at this time, testing for any organism other than E. coli O157:H7 would not be acceptable validation of a CCP to prevent, eliminate, or reduce *E. coli* O157:H7. However, if at some point in the future, establishments can demonstrate that there is an organism that can be used as an indicator organism for E. coli O157:H7, this organism could be used for validation of CCPs addressing *E. coli* O157:H7."

The regulatory position on the use of indicator organisms for in-plant validations needs to be clarified. Some years ago Australia obtained FSIS agreement to use as an in-plant indicator organism the *Klebsiella oxytoca* strain NRRL B-199 for a commercial evaluation of a hot water decontamination system (Sofos and Smith, 1998). We believe that a non-pathogenic strain of *E. coli* would also be suitable. The criterion for choosing a surrogate organism for testing purposes should be that it responds in the same way to the intervention as representative strains of *E. coli* O157:H7 do.

The Notice does not define the reduction of E. coli O157:H7 required. There is no guidance to quantify the required reduction of the organism. It is therefore not possible to perform a validation that will ensure that the goal of no detectable E. coli O157:H7 will be met. It is suggested, that the use of a suitable measure such as coliform counts could be used in routine plant operations to demonstrate the effectiveness of an intervention.

Since the introduction of the final pathogen reduction rule in 1996 and the attendant requirement for slaughtering establishments to monitor *E. coli* and *Salmonella*, it has been forbidden in Australia for *E. coli* to be deliberately introduced to a slaughter floor for evaluation purposes. Clear guidelines are needed for use of *E. coli* as an indicator organism. They must satisfy both regulators and processors. The guidelines must include details of disposition of test carcases and carcases that are adjacent to them during slaughter and chilling.

Literature cited

Altekruse, S. F., Timbo, B. B., Mowbray, J. C., Bean, N. H. and Potter, M. E., 1998. Cheese-associated outbreaks of human illness in the United States, 1973 to 1992: sanitary manufacturing practices protect consumers. Journal of Food Protection, 61 (10), 1405-1407.

AMSA 1999. The role of microbiological testing in beef food safety programs. The scientific perspective. Consensus of the 1999 Symposium. American Meat Science Association.

Bovee, E. H. G., Kruijf, N, de., Jetten, J. and Barendsz, A. W., 1997. HACCP approach to ensure the safety and quality of food packaging. Food Additives and Contaminants, 14 (6/7), 721-735.

Brown, M. H., Gill, C.O., Hollingsworth, J., Nickelson II, R., Seward, S., Sheridan, J. J.,Stevenson, T., Sumner, J. L., Theno, D. M., Usborne W. R., Zink, D., 2000. Review - The role of microbiological testing in systems for assuring the safety of beef. International Journal of Food Microbiology, 62, 7-16.

Castillo, A, Dickson, J S, Clayton, R P, Lucia, L M, and Acuff, G R (1998). Chemical dehairing of bovine skin to reduce pathogenic bacteria and bacteria of fecal origin. J Food Prot. 61, 623-625.

Davies, M. H. et al (2000). Production factors that influence the hygienic condition of finished beef cattle. Veterinary Record. 2000, 146, 179-183.

Delazari, I, Iaria, S T. Riemann, H P, Cliver, D O, and Mori, T 1998 Removal of Escherichia coli O157:H7 from surface tissues of beef carcasses inoculated with wet and dry manure. J Food Prot. 61 (10), 1265-1268.

Dorsa, W J, Cutter, C N, and Siragusa, G R. 1997 Effects of steam-vacuuming and hot water spray wash on the microflora of refrigerated beef carcass surface tissue inoculated with Escerichia coli O157:H7, Listeria innocua and Clostridium sporogenes. J Food Prot. 60(2),114-119.

Elder, R O, Kenn, J E, Siragusa, G R, Barkocy-Gallagher G A, Koohmarie,M, and Laegreid, W W. 2000. Correlation of enterohemorrhagic Escerichia coli O157 prevalence in feces, hides, and carcasses of beef cattle during processing. Proc. Natl Acad. Sci USA 97 (7) 2999-3003

Eustace, I J and Vogler, T (1998) Project MSQS.002, Pre-slaughter holding/cleaning techniques. Report to Meat Research Corporation, Australia.

Gill, C.O., Badoni, M., and Jones, T. (1996) Hygienic effects of trimming and washing operations in a beef-carcass-dressing process. Journal of Food Protection, 59 (6), 666-669.

Gill, C. O. and Bryant, J. (1997) Assessment of the hygienic performance of two beef carcass cooling processes from product temperature history data or enumeration of bacteria on carcass surfaces. Food Microbiology, 14 (6), 593-602.

Gill, C O, Bryant, J, and Bedard, D 1999 The effects of hot water pasteurising treatments on the appearances and microbiological conditions of beef carcass sides. Food Microbiology 16 281-289

Hardin M D, Acuff, G R, Lucia, L M, Oman, J S, and Savell, J W 1995 Comparison of methods for decontamination from beef carcass surfaces. J Food Prot. 58 (4) 368 374.

Huffman, R D 2002 Current and future technologies for the decontamination of carcasses and fresh meat Meat Science 62, 285-294

ICMSF, 1986. Microorganisms in Foods 2. Sampling for microbiological analysis; principles and specific applications, 2nd edition. Roberts, T. A., Bryan, F. L., Christian, J. H. B., Kilsby, D., Olson, J. C. Jr., and Silliker, J. H. (editors). University of Toronto Press, Toronto.

Kain, M L, Kochevar, S L, Sofos, J N, Belk, K E, Rossiter, C, Reagan J O, and Smith G C (2002) Relationships of live animal scores for ambulatory status, body condition, hide cleanliness, and fecal matter consistency to microbiological contamination of dairy cow carcases. Dairy, Food and Environmental Sanitation 21, 990 996

Kochevar, S L, Sofos, J N, Bolin, R R, Reagan, J O, and Smith G C 1997. Steam vacuuming as a pre-evisceration intervention to decontaminate beef carcasses. J Food Prot 60 (2) 107-113

McEvoy J M, Doherty, A M, Finnerty, M, Sheridan J J, McGuire, L, Blair, I S, McDowell, D A, and Harrington, D (2000). The relationship between hide cleanliness and bacterial numbers on beef carcasses at a commercial abattoir. Letters in Applied Microbiology 30, 390-395.

Phebus, R K, et al 1997 Comparison of steam pasteurisation and other methods for reduction of pathogens on surfaces of freshly slaughtered beef. J Food Prot. 60 (5) 476-484

Samelis, J et al 2002 Effect of acid adaptation on survival of Escherichia coli O157:H7 in meat decontamination washing fluids and potential effects of organic acid interventions on the microbial ecology of the meat plant environment. J Food Prot. 65, 33-40

Schnell, T D, et al (1995) Dehairing of beef carcasses as an intervention to reduce microbial load and improve visual cleanliness. Conf. Proc. IFT Annual Meeting 140.

Schothorst, van-, M., 1996. Sampling plans for *Listeria monocytogenes*. Food Control, 7 (4/5), 203-208.

Smith, D, Blackford, M, Younts, S, Moxley, R, Gray, J, Hungerford, L, Milton, T and Klopfenstein, T. 2001. Ecological relationships between the prevalence of cattle shedding

Escherichia coli O157:H7 and characteristics of the cattle or conditions of the feedlot pen. J Food Prot. 64(12) 1899-1903.

Theno, D. M., 1995. Microbial control: the merits of HACCP over end product testing. IFT Annual Meeting, 1995.

Schothorst, van-, M., 1996. Sampling plans for *Listeria monocytogenes*. Food Control, 7 (4/5), 203-208.

Vanderlinde, P. B. et al (1996). *E. coli* on Australian Beef. Meat Research Corporation Research Project CS.268.

Van Donkersgoed, J, Jericho, K W, Grogan, H and Thorlakson, B (1997) Preslaughter hide status of cattle and the microbiology of carcasses. J Food Prot. 60, 1502-1508.