



Original dated
Covering letter revised

15 April 2003
8 May 2003

TO WHOM IT MAY CONCERN

MONBEEF PTY LTD ESTABLISHMENT 0952 E. COLI 0157:H7 STATEMENT OF COMPLIANCE

This statement should be read in conjunction with the Australian Quarantine Inspection Service (AQIS) response to the FSIS, Control of *ESCHERICHIA COLI* 0157:H7 by the Australian beef industry³.

Only product that is compliant with the HACCP requirements and tested negative for e. coli 0157:H7 is shipped

In response to your request concerning food safety, Monbeef Establishment 952 confirms it has process controls, including its HACCP, that are designed to control microbiological hazards (for example E.coli 0157:H7). The HACCP plan has recently been reassessed on 12 December 2002 in accordance with 'Federal Register Notice 9 CFR Part 417 Docket Number 00-022N dated 7 October 2002 – E.coli contamination of beef products'. An outline of these process controls is on the following pages.

Monbeef Establishment 952's reassessment of its HACCP plan has recently (dated 31 January 2003) been reviewed by the Australian Quarantine and Inspection Service (AQIS) in accordance with Federal Register Notice 9 CFR Part 417 Docket Number 00-022N.

Monbeef Establishment 952 has reassessed its HACCP by February 4th 2003 in line with 9 CFR 417 E.coli 0157:H7 Contamination of beef products, and FSIS Directive 10,010.1 and that due to the continuous and effective operation of the sanitary Standard Operating Procedures, Work Instructions, Meat Hygiene Assessment, Escherichia Coliforms and Salmonella Monitoring (ESAM), current CCP's, Corrective Action SOP and Pre-shipment Review, then E.coli 0157:H7 is considered to be a hazard that is not likely to occur in our finished product because of interventions employed at this plant and stated in this letter.

This conclusion was reached after assessing the following information:

- Results from the February 2000 Report on the Microbiology of Australian Meat shows that E.coli 0157:H7 was not found in cartons of frozen product on a national basis. Correspondence from Alliance Consulting who conducted the above survey shows that E.coli (including 0157:H7) was not detected in Monbeef product.
- Customer feedback reports, on file showing that E.coli 0157:H7 has not been detected on Monbeef product processed by them.
- The absence of any feedback indicating that Monbeef product has been involved in any positive finding of E.coli 0157:H7.
- Monbeef undertakes verification microbiological testing for E.coli 0157:H7 prior to despatch. At Monbeef 5 cartons in each 700 cartons of product destined for grinding are tested on a lot basis, between 10 and 15 cartons are tested each day. Testing commenced in 1998 and since then approximately 11,300 cartons of manufacturing meat have been sampled (including trim, sirloin and cheeks). This testing represents 0.0005%⁽⁸⁾ of our total production (the Australian average tested is 0.00016%⁽³⁾ and the USDA is 0.000073%⁽³⁾). There have been no positive detections of E.coli 0157:H7 on Monbeef product.

Monbeef Establishment 952 is committed to producing the highest quality, food safe product possible.

Yours faithfully


David Clapham
QA Manager

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Commercial in confidence

PROCESS CONTROLS

Our HACCP is supported by management tools such as Meat Hygiene Assessment (MHA) and Standard Operating Procedures (SOP's) which are part of our Australian Quarantine and Inspection Services (AQIS) approved Meat Safety Quality Assurance (MSQA) program. AQIS are the Australian equivalent to FSIS.

Pre-requisite Standard Operating Procedures (SOPs), equivalent to Sanitation Standard Operating Procedures (SSOPs), and individual operator work instructions (WI's) are required as part of MSQA. They are important in ensuring that there is an absolute minimal risk of microbiological contamination of product, including contamination with *E. coli* O157:H7.

MHA requires the company to monitor the performance of the process at each operational position on the processing line to ensure that WI's are performed as required. At Monbeef this monitoring is conducted a minimum of daily at Pre Slaughter Livestock Handling, Humane Slaughter and Hygienic Dressing, Boning and Storage and Despatch by the process owners (Foreman/supervisor) and independently verified by QA Officers.

Verification is done by monitoring of product (cattle, sides and cartons) to ensure that meat being produced using the WI's is safe, wholesome and suitable for human consumption and not contaminated with hide, hair, faeces, ingesta or other contaminants from the processing environment. The hygiene of cattle is checked prior to slaughter, the hygiene of sides of beef is checked prior to them entering the boning room and the hygiene of cartons of meat is checked prior to cartons entering refrigeration. Cattle are assessed for cleanliness every mob, sides of beef are assessed based on a lot size of one hours production, and carton product is assessed based on a lot size of half an hours production. This is the first level of verification and provides real time feedback to the process to enable effective corrective actions to be taken.

A value called a Defect Rating describes product hygiene and a value called a Conformity Index describes the process control. Assessment of trends is made from both process and product monitoring to identify the level of control attained by the company during operations. Trigger levels are set to require corrective actions designed to keep the process and product within predefined parameters. MHA is verified by AQIS weekly.

SOP's are based on Good Manufacturing Practices (GMP)⁽¹²⁾ and include regulatory and customer requirements. Pre-requisite SOP's are in operation in addition to MHA. These pre-requisite programs underpin the sanitary program and ensure that the operational environment, equipment and personnel are not at risk of contaminating the product. The SOPs cover areas such as personal hygiene, pre operational hygiene, operational hygiene, cleaning and sanitation, chemicals and food additives, water supply as well as vermin and pest control.

Compliance to these SOP's is verified by QA staff and by internal audits conducted by qualified food safety auditors. Pre operational, operational and personal hygiene are all monitored and verified. The entire system is overseen by AQIS. AQIS maintain a full time presence during operations of a veterinary officer and a food safety officer who are responsible to ensure regulatory compliance and public food safety.

It is important to note that Monbeef has a QA Manager (and staff) who are independent of the Production Manager. The aim of this approach is to ensure that food safety issues are addressed independently of the production process and the final decision in any areas of conflict between QA and production rest at a higher level of the organisation.

As food handlers all operators are screened medically and once cleared undergo company induction prior to employment. Training in relevant sanitation SOP's and WI's is comprehensive and competency based i.e. operators work under close guidance until assessed as competent. Qualifications expire every 6 months and competency is reassessed by trained and qualified company assessors.

The staff turnover at Monbeef is around 13%⁽⁸⁾ so the work force is very stable and well trained. This stability assures a high level of competence in our operators and this is reflected in the high quality and hygiene of the product.⁽³⁾

In addition to verification testing for *E.coli* O157:H7 in cartons (using Meridean Bioscience Inc, Immunocard STAT), Monbeef samples carcasses for generic *E.coli* and Total Viable Counts (TVC) expressed as colony forming units per square centimetre (CFU/cm²). The incidence of *E.coli* O157:H7 on carcasses is very low⁽³⁾ and the usefulness of testing for it is doubtful. Generic *E.coli* is a good benchmark organism as its' presence indicates the potential for *E.coli* O157:H7 to be present and as such, process controls designed to reduce the incidence of generic *E.coli* will reduce the chance of *E.coli* O157:H7 being on the carcass. ANY incidence of generic *E.coli*⁽⁹⁾, OR a TVC above 50 CFU/cm²⁽¹⁰⁾ triggers corrective action which includes a review of WI's, preventative measures and monitoring records.

Microbiological swabs are also used to verify pre operational, operational and personal hygiene to ensure a safe processing environment. Any TVC greater than 5CFU/cm² ⁽¹⁰⁾ results in corrective actions

Our HACCP reassessments have identified the following practises and procedures within our process that are specifically designed to eliminate contamination of carcasses. These practices have a multiple hurdle effect in reducing the likelihood of finding any pathogenic bacteria (including E.coli 0157:H7) on final product:

Pre slaughter

- ✓ HACCP-based QA programs operate increasingly on farms (cattlecare program) ⁽³⁾
- ✓ QA program in place for livestock transport (truckcare program) for 90% of our deliveries ⁽³⁾⁽⁸⁾
- ✓ QA and mandatory government accreditation for saleyards.
- ✓ All stock purchased have a Vendor Declaration and are traceable to property of origin. ⁽⁶⁾⁽¹⁷⁾
- ✓ Cattle are handled quietly and humanely in accordance with industry best practice. ^(13, 14, 15, 16)
- ✓ Lairage, pens and force up are built to Temple Grandin guidelines to minimise stress. ^(13, 14, 15, 16)
- ✓ Pre slaughter handling of cattle assessed to Temple Grandin guidelines to minimise stress. ^(13, 14, 15, 16)
- ✓ All cattle have ante mortem inspection before slaughter by AQIS veterinary officer. ⁽¹⁷⁾
- ✓ Cattle with suspect conditions are isolated for AQIS veterinary officer disposition. ⁽¹⁷⁾
- ✓ Lairage is away from processing building to eliminate possibility of air born cross contamination but is close enough to allow stress free forceup and handling. ⁽¹⁷⁾
- ✓ Stock water troughs are kept clean and fed with clean potable water. ⁽¹⁷⁾
- ✓ Lairage is kept clean and pens are hosed out between drafts. ⁽¹⁷⁾
- ✓ Cattle are washed prior to slaughter, assessed for cleanliness and presented with hides free from visible faeces. ⁽¹⁷⁾
- ✓ Traceability is maintained throughout the slaughter process. ⁽¹⁷⁾

Slaughter

Hide on area

- ✓ Humane slaughter of cattle assessed to Temple Grandin guidelines. ^(13, 14, 15, 16)
- ✓ Line speeds are less than 30 per hour (this allows adequate time for operators to hygienically dress carcasses and check own work for zero tolerance control). ⁽¹⁾⁽¹⁷⁾
- ✓ Hide removal area is separate to hide off area. ⁽¹⁷⁾
- ✓ Air flow on the slaughter floor is from the hide off towards the hide on area (clean to dirty). ⁽¹⁾⁽¹⁷⁾
- ✓ Faeces and ingesta treated as zero tolerance on dressed carcass. ^(1, 3)
- ✓ Cattle soiled during forceup are hosed to remove faecal contamination (on the dry landing prior to hoisting and subsequent dressing). ^(1, 17)
- ✓ The oesophagus is occluded prior to hoisting to prevent ingesta being regurgitated. ⁽¹⁾
- ✓ Prevention of carcass to carcass cross contamination by adequate spacing on the rail. ^(1, 17)
- ✓ Hide is damp during removal to prevent dust/aerosol from hide fallout. ^(1, 3)
- ✓ Udders removed in one piece with no milk spillage. ^(1, 3, 17)
- ✓ Milk treated as zero tolerance on dressed carcass. ⁽¹⁾
- ✓ Bung is tied and bagged after rumping and prior to hide puller. ⁽¹⁾
- ✓ Hide is removed using GMP designed to prevent cross contamination as follows: ⁽¹⁷⁾
 - Procedures commenced with clean hands and sanitised knives and equipment.
 - All equipment which contacts the carcass is sanitised between each carcass and whenever contaminated. ⁽¹⁾
 - Opening cut kept as small as possible. ⁽¹⁾
 - Subsequent cuts are spear cuts. ⁽¹⁾
 - Knives sanitised after each cut through the hide (two knife system). ⁽¹⁾⁽³⁾
 - Outside of hide not allowed to contact cleared/dressed surface. ⁽¹⁾
 - Hide flapping minimised to reduce hide fallout and cross contamination. ⁽¹⁾
 - Operators check their own work. ⁽³⁾

Hide off area

- ✓ Procedures commence with clean hands and sanitised knives and equipment. ⁽¹⁾
- ✓ All equipment which contacts the carcass is sanitised between each carcass and whenever contaminated. ⁽¹⁾
- ✓ Use of a ball point blade on the brisket saw with the leading two teeth filed down to help prevent rupturing the paunch. ⁽⁸⁾
- ✓ AQIS conducts public food safety/pathology inspection on all sides of beef. ⁽¹⁷⁾
- ✓ The Trim step is a designated Critical Control Point (CCP) ⁽¹²⁾ controlling faeces, ingesta, milk, urine, bile and pathology on the dressed carcass. This is to ensure that sides are hygienically dressed prior to entering the boning room. ⁽¹⁾⁽¹⁷⁾
- ✓ Necks are trimmed to remove sticking wound. ⁽¹⁾⁽¹⁷⁾
- ✓ Operators check own work. ⁽³⁾
- ✓ Air flow and pedestrian traffic are controlled to prevent cross contamination. ⁽¹⁾⁽¹⁷⁾

Boning Room

- ✓ Sides boned hot with no delay after dressing. ⁽¹⁷⁾
- ✓ Strict time and temperature targets are set and maintained to ensure product is under refrigeration within 60 minutes of commencement of boning. ^(1, 18, 19, 20, 21, 22)
- ✓ Boning room is air conditioned to maintain a temperature of 10°C or below. ⁽¹⁷⁾

Storage and Despatch

- ✓ Strict time and temperature targets are set and maintained to ensure product is down to a safe temperature of 7°C within 7 hours of being placed under refrigeration for freezing (CCP) or 13 hours for chilled vacuum packed products (CCP) with a pre-defined maximum allowable growth in bacteria. ^(1, 17, 18, 19, 20, 21, 22)
- ✓ Product is stored at a temperature to ensure minimal growth of pathogens. (frozen -18°C (CCP), Fresh -1.8°C to +2°C (CCP)) ^(1, 11, 17, 18, 19, 20, 21, 22)
- ✓ Products are despatched in insulated refrigerated trucks/containers. ^(1, 17)

Further detail can be provided upon request.

References/Comments:

1. FSIS, 2002, Guide on minimising risk from 0157 and salmonella
2. Food Science Australia 2003, comments on FSIS 2002 guide on minimising risk from 0157 and salmonella.
3. AQIS, 2003, Control of *ESCHERICHIA COLI* O157:H7 by the Australian beef industry
4. USDA, 2002, Federal Register 9 CFR Part 417 00-022N
5. J. R. Ransom et al., 2001, Evaluation of methods for sampling rectal/colonic feces, hides and carcasses to test for presence of *Escherichia coli* 0157:H7 and *Salmonella* spp.
6. R. T. Bacon et al, 2001, Microbial mapping III. Determining microbiological counts on beef subprimal cuts during/following fabrication with and without microbiological decontamination treatments
7. National Vendor Declarations are mandatory.
8. Statistical analyses of Monbeefs' historical records.
9. Required under AQIS MHA.
10. Corrective action trigger developed at Monbeef and based on historical records and trends analyses.
11. Australian Cold Chain Code of Practise
12. J.N. Sofos et al., 1999, Processes to Reduce Contamination with Pathogenic Microorganisms in Meat ("Decontamination interventions, however, need to be applied in conjunction with good manufacturing practices in the spirit of the principles of HACCP")
deleted
13. deleted
14. Temple Grandin, Ways to Facilitate Animal Movement
15. Temple Grandin, Lowering Stress To Improve Meat Quality and Animal Welfare In Cattle
16. Temple Grandin - Providing less stressful pre slaughter handling
17. Codex Alimentarius, Meat and Meat Products, Volume 10.
18. Process Validation Report Hot Boning Procedures at Monbeef P/L dated 14 Oct 98
19. Process Validation Report Hot boned primal chilling procedures at Monbeef P/L dated 13 Nov 98
20. HACCP Validation report on Processing of Hot Boned Beef at Monbeef P/L dated November 1999.
21. Process Validation final report on alternate packing procedures at Monbeef P/L dated July 2001.
22. Process Validation correspondence on alternate packing procedures at Monbeef P/L dated 31 July 2001.