

06 January 2017

To Whom It May Concern:

MONBEEF PTY LTD ESTABLISHMENT 0952
HACCP, E. COLI O157:H7, SRM and ANIMAL WELFARE STATEMENT OF COMPLIANCE

This statement should be read in conjunction with the Australian Department of Agriculture response to the FSIS, Control of *ESCHERICHIA COLI* O157:H7 by the Australian beef industry³. This statement replaces all previous statements and reflects the current approved HACCP. Sampling figures are up to and including 06 January 2017. Our HACCP was re-assessed most recently on 24 May 2016.

Only product that is compliant with the approved HACCP requirements 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 O157:H7). Monbeef Establishment 952 has reassessed its HACCP in line with 9 CFR 417 E.coli O157: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, Preventative Action Plans and Pre-shipment Review, then E.coli O157:H7 is considered to be a hazard that has the potential to occur in our finished product but likelihood is minimized because of interventions employed at this plant and stated in this letter. This conclusion was reached after assessing the following information:

- ✓ Results of the February 2005 Report on the Microbiology of Australian beef and sheepmeat shows that E.coli O157:H7 was not found in cartons of frozen product on a national basis. (24)
- ✓ Results from the February 2000 Report on the Microbiology of Australian Meat shows that E.coli O157: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 O157:H7) was not detected in Monbeef product. (23)
- ✓ Customer feedback reports, on file showing that STEC (including E.coli O157: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 STEC (including E.coli O157:H7).
- ✓ E.coli O157:H7 is a hazard with a HACCP Plan Significance Score requiring a CCP in line with Department of Agriculture Meat Notice 2011/04 (26). Although this is addressed at CCP S1 (Zero Tolerance), The HACCP team also added the testing for E.coli O157:H7. Product is not released until Pre-shipment review is complete and Lot testing confirms that the result for STEC's (including E.coli O157:H7) is "Not Detected". Re-testing and sub-lotting is not allowed, the original result stands. Testing is done by a Department of Agriculture Approved External Laboratory (currently Symbio).
- ✓ In the event of a presumptive positive, confirmatory testing would be done off site at a Department of Agriculture Biosecurity approved laboratory using Department of

Agriculture/FSIS approved methodology in accordance with our Approved Arrangement. The sampling and testing is approved and overseen by Department of Agriculture Biosecurity using approved methods only (with FSIS equivalence). Our testing protocol was revised in October 2007 to require a minimum of 60 samples per test (N60) with a minimum composite sample size of 375g. Sampling and testing was revised in June 2010 to comply with Department of Agriculture Meat Notice 2010/03 and again in July 2012 to comply with Department of Agriculture Meat Notice 2012/01 (26)

- ✓ In the 12 Months to 06 January 2016, in excess of 80 000 cartons of manufacturing meat have been sampled (using current N60 protocols). There has been no positive detection of E.coli O157:H7 on Monbeef product. Compliance with Department of Agriculture testing is now endorsed on the health certificate as issued by Department of Agriculture for each required consignment. Under the previous sampling protocols, there had been no detections of E.coli O157:H7 on Monbeef product
- ✓ Our testing procedures for E.coli O157:H7 have been audited recently by the Department of Agriculture and found to be acceptable (commercial testing of raw materials destined for grinding in the US (26)).
- ✓ The incidence of O157:H7 on Monbeef product is 0.0% (based on testing and results as above). This indicates that process controls currently in place at this plant (including the HACCP) reduce the incidence of E.coli O157:H7 to an acceptable level of “Not Detectable”⁽¹⁾.
- ✓ Since June 2012, Monbeef has further validated the HACCP Plan by testing each E.coli O157:H7 sample for the Big 6 STEC and has had 5 potential positives from 529500Cartons

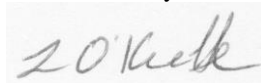
SRM is removed in accordance with FSIS requirements (Federal Register (docket No 03-025IF) which specifies “Prohibition of the use of specified risk materials for human food and Requirements for the disposition of non-ambulatory disabled cattle”), SRM is removed on the slaughter floor. No SRM is allowed into the boning room and is most certainly NOT in our product. Downers and non ambulatory cattle are not slaughtered for export markets.

Animal Welfare is integral to our slaughter operations and our Animal Care Statement as approved and overseen by Department of Agriculture is verified both internally and by annual 3rd party audit.

Please read the following pages for further details.

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

Yours faithfully



Lynlee O'Keefe (B.Sc)
QA Manager
Monbeef Pty Ltd

PROCESS CONTROLS - general

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 (Department of Agriculture) Approved Arrangements (AA's). Department of Agriculture are the Australian equivalent to FSIS. Pre-requisite SOPs, equivalent to Sanitation Standard Operating Procedures (SSOPs), and individual operator work instructions (WI's) are required as part of AA's. 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 Dispatch 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 (not contaminated with hide, hair, faeces, ingesta or other foreign 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. This is the first level of verification (based on organoleptic assessment) and provides real time feedback to the process to enable effective/timely 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 timely corrective actions designed to keep the process and product within predefined parameters. MHA is verified by Department of Agriculture 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 animal welfare, personal hygiene, pre operational hygiene, operational hygiene, cleaning and sanitation, chemicals and workplace substances, water supply, calibration, security, food defense 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 Department of Agriculture and Water Resources. DAWR 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 12 months and competency is reassessed by trained and qualified company assessors. The staff turnover at Monbeef is around less than 10%(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(CCP), Monbeef samples carcasses for generic *E.coli*, Coliforms and Total Viable Counts (TVC) expressed as colony forming units per square centimetre (CFU/cm²). The incidence of *E.coli* O157:H7 on cattle 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 or Coliform count above 20 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 practices 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 O157:H7) on final product:

Pre slaughter

- ✚ ☐ HACCP-based QA programs operate increasingly on farms (Cattlecare and Livestock Production Assurance programs) (3)
- ✚ ☐ QA program in place for livestock transport (Truckcare program) for 95% of our deliveries (3)(8).
- ✚ ☐ QA and mandatory government accreditation for saleyards.
- ✚ ☐ All stock purchased are identified in accordance with the National Livestock Identification Scheme (NLIS) and have a National Vendor Declaration and are traceable to property of origin using Property Identification Codes and Radio Frequency Identification Tags.(6) (17)
- ✚ ☐ Cattle are handled quietly and humanely in accordance with industry best practice, Australian Standards and our approved Animal Care Statement. (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 Department of Agriculture veterinary officer.(17)
- ✚ ☐ Cattle with suspect conditions are isolated for Department of Agriculture 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 force up 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 – Humane Slaughter and Hygienic Dressing

Hide on area

- ✚ ☐ Humane slaughter of cattle assessed to Temple Grandin guidelines. (13, 14, 15, 16)
- ✚ ☐ Line speeds are 30 or less 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, ingesta, milk and urine are treated as zero tolerance on dressed carcass. (1, 3)
- ✚ ☐ Cattle soiled during force-up 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) (25)
 - ✓ ☐ Subsequent cuts are spear cuts. (1)(25)
 - ✓ ☐ 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)

Slaughter – Humane Slaughter and Hygienic Dressing

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)
- ✚ ☐ Spinal chord is removed intact with Ezyvac.
- ✚ ☐ Department of Agriculture conducts public food safety/pathology inspection on all sides of beef. (17)
- ✚ ☐ The Final trim step on dressed sides and offal is a designated Critical Control Point (CCP)(12) controlling faeces, ingesta, milk, urine. This is to ensure that sides are hygienically dressed prior to entering the boning room and that offal is packed free from ZT defects. Trimming of Headmeats is a CCP. (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^oC or below. (17)

Storage and Dispatch

- ✚ ☐ Strict time and temperature targets are set and maintained to ensure product is down to a safe temperature of 7^oC within 10 hours of being placed under refrigeration for freezing (CCP) or 2^oC within 24 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^oC , Fresh –1.8 ^oC to +2 ^oC (CCP is = or < than 4 ^oC)) (1, 11, 17, 18, 19, 20, 21, 22)
- ✚ ☐ Products are dispatched in insulated refrigerated trucks/containers. (1, 17)

Further detail can be provided upon request.

References/Comments:

1. FSIS, 2002, Guide on minimising risk from O157 and salmonella
2. Food Science Australia 2003, comments on FSIS 2002 guide on minimising risk from O157 and salmonella.
3. Department of Agriculture, 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/colonal feces, hides and carcasses to test for presence of *Escherichia coli* O157: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 Department of Agriculture MHA.
10. Corrective action trigger developed at Monbeef and based on historical records and trends analyses.
11. Australian Cold Chain Code of Practice
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")
13. National/Australian Standard for the Humane Handling of Livestock at Slaughter Establishments Processing Meat for Human Consumption.
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 and The Australian National Animal Welfare Standards at Livestock Processing Establishments.
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.
23. Report on the Microbiology of Australian meat – February 2000.
24. Report on the Microbiology of Australian beef and sheepmeat - February 2005.
25. Factors contributing to the microbiological contamination of beef carcasses - February 2005.
26. Department of Agriculture MEAT Notice 2012/01 (*Escherichia coli* O157:H7 testing of raw ground beef components intended for export to the United States and it's Territories