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Improving the Effectiveness of Food Safety Regulation to Minimise Shiga Toxin-Producing *Escherichia coli* Contamination in Fermented Meat Products

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Grey Literature

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AN EXTENDED ABSTRACT

Background: The consumption of uncooked comminuted fermented meat (UCFM) contaminated with Shiga toxin-producing *Escherichia coli* (STEC) poses a public health risk. The severity of such a health risk can be demonstrated by an outbreak that occurred in South Australia in 1995, where the consumption of Mettwurst contaminated with *E. coli* O111:NM resulted in the death of one child, haemolytic uraemic syndrome in twenty-two children, and permanent adverse health effects in at least six children and one 60 years old consumer. The Australian meat industry incurred an estimated loss of more than $A 400 million. In response to the outbreak, the Australian Government introduced an emergency measure in 1996 to ensure the safety of UCFM products.

A key performance criterion prescribed in the emergency measure – that the UCFM production process must reduce the number of *E. coli* organisms by 99.9% (a 3-$\log_{10}$ reduction) or greater – could not be effectively implemented by the industry or enforced by the health authorities. This was largely due to a lack of an objective means to determine compliance.

Food Standards Australia New Zealand (FSANZ) undertook a review of the emergency measure between 2001 and 2003. This paper describes the risk analysis FSANZ undertook to improve the effectiveness of food safety regulation in this area.

Aims: To develop a set of outcome-based regulatory measures to replace a prescriptive requirement of a 3-$\log_{10}$ reduction of *E. coli*, designed to minimise STEC contamination in UCFM.

Study design: Food safety risk analysis.

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Place and Duration of Study: FSANZ, Canberra, Australia, between November 2001 and July 2003.

Methodology: The ability of Australian UCFM manufacturers to effectively implement the processing requirement of a 3-$\log_{10}$ reduction in *E. coli* concentration was assessed using an Excel® based predictive model developed by the University of Tasmania that estimates the inactivation of generic *E. coli* during the UCFM manufacturing process. Temperature and time parameters of fermentation and maturation applied to the production of UCFM for sale in Australia were collected during 2002 and 2003 and applied to the predictive model.

Outcome-based regulatory measures to minimise STEC contamination in UCFM were developed based on (1) the conclusions of a quantitative microbiological risk assessment (based on point estimates), (2) close consultation with the Australian UCFM sector and food regulation enforcement authorities, and (3) a regulatory impact assessment.

Tools to facilitate effective implementation of the outcome-based regulatory measures were developed between 2004 and 2005 with the assistance of a national expert advisory panel on UCFM safety. This panel was comprised of food safety and technical experts from the Australian smallgoods sector and state enforcement authorities.

Results: Assessment of 96 production protocols used by Australian UCFM manufacturers in April 2002 using the predictive *E. coli* inactivation model showed that only 19% of the protocols were capable of achieving greater than or equal to a 3-$\log_{10}$ reduction of *E. coli*. Up to 51% of the protocols assessed achieved less than 2-$\log_{10}$ reduction of *E. coli*. The remaining protocols were capable of achieving a maximum reduction of *E. coli* between 2 and less than 3-$\log_{10}$. Among the 96 production protocols assessed, the highest level of inactivation of *E. coli* potentially achievable was 9.08 $\log_{10}$ and the lowest was 0.13 $\log_{10}$. A relatively long period of maturation and a relatively high temperature during the maturation phase contributed to the bulk of *E. coli* inactivation achieved during the manufacture of UCFM.

Production protocols resubmitted from UCFM manufacturers in the state of Victoria, following the initial assessment, showed a steady improvement of capability in achieving greater than or equal to a 3-$\log_{10}$ reduction of *E. coli*. This was achieved by making adjustments to the time and temperature parameters of the production processes. Despite these adjustments, 34% of the resubmitted protocols failed to meet the requirement of reduction of *E. coli* by 3-$\log_{10}$.

Consultations with technical experts of the Australian smallgoods sector and enforcement authorities identified several additional issues with the 3-$\log_{10}$ reduction requirement. These included:

- the rationale behind of the need for a 3-$\log_{10}$ reduction of *E. coli* when safe UCFM products can be produced using deep muscle meat and when subject to close adherence to operational hygiene, knowing the fact that the extent of STEC contamination in deep muscle meat is very low;
- doubts on the adequacy of a 3-$\log_{10}$ reduction of *E. coli* when raw ingredients used to produce UCFM contain excessively high numbers of STEC;
- enforcement authorities did not have the tools to verify whether manufacturers of UCFM had achieved a 3-$\log_{10}$ reduction of *E. coli*; and
- the science underpinning the mandatory requirement of a 3-$\log_{10}$ reduction of *E. coli* in manufacturing UCFM was difficult to comprehend by members of the

industry, let alone their ability to demonstrate compliance against the requirement.

A microbiological risk assessment was undertaken by FSANZ to provide a scientific basis for the identification and development of effective outcome-based regulatory measures to minimise STEC contamination in UCFM products. The main conclusions of the risk assessment were that:

- the ingestion of as few as 1 STEC could lead to severe adverse health consequences in susceptible individuals;
- children under the age of 6 are more likely to develop severe complications from STEC infections;
- based on the available data at the time, it was estimated that a mean of 0.15 STEC/100 g was present in approximately 7.2% of the UCFM manufactured in Australia; and
- under this level of STEC contamination, it was estimated that the likelihood of encountering 1 STEC organism by UCFM consumers under the age of 6 years old would be approximately 1 in 174 UCFM meals. If UCFM was produced under minimum (time and temperature) processing conditions, this likelihood would shift to approximately 1 in 3 UCFM meals.

The above findings of the risk assessment established the basis for further regulatory interventions in UCFM production. The implementation of hazard analysis critical control point (HACCP) based food safety programs, together with a number of specific requirements, was identified as the preferred option to replace the prescriptive processing requirement of a 3-log10 reduction of *E. coli*. This risk management decision took into consideration of the issues identified during the consultations with the Australian smallgoods sector and enforcement authorities, and the factors of:

- a mandatory requirement for having HACCP based food safety programs developed and implemented by the UCFM sector would impose minimal compliance costs because HACCP-based food safety systems have been introduced into the Australian UCFM sector on a voluntary basis since 1998; and
- the policy of the Council of Australian Governments requires national food standards to be outcome based.

Together with the requirement of having HACCP based food safety programs implemented, the outcome-based regulatory measures specified validation and verification procedures to ensure that the number of *E. coli* in the final product complies with limits specified for UCFM in Standard 1.6.1 of *the Australian and New Zealand Food Standards Code* (n=5, c=1, m=3.6, M=9.2). UCFM manufacturers were also required to provide evidence to demonstrate that their production processes are capable of handling the variations in the level of *E. coli* contamination in the ingredients. The latter requirement puts UCFM manufacturers in charge of product safety by allowing the flexibility in raw material selection. In addition, it requires that appropriate adjustments in manufacturing parameters be made to cope with the extent of fluctuation of *E. coli* contamination in the raw materials, to ensure UCFM safety.

To assist the UCFM sector to implement HACCP based food safety programs, a Protocol for Assessing HACCP Based Food Safety Programs in the UCFM Sector (the protocol) has been developed by FSANZ in association with experts in manufacturing smallgoods and enforcing food safety regulations. The protocol has been adopted by the state enforcement authorities for assessing UCFM manufacturers' compliance against the requirement of

implementation of HACCP based food safety programs. To raise the overall level of skills and knowledge on food safety in the UCFM sector, a set of Competency Criteria for UCFM Manufacturers on food safety skills and knowledge has been developed and incorporated into an industry training package. The package was developed jointly by FSANZ, experts in manufacturing smallgoods and enforcing food safety regulations, and the National Meat Industry Training Advisory Council. It targets those who intend to enter the UCFM manufacturing sector. This training package has been made available nationwide through technical and further education institutes.

Conclusion: Careful considerations ought to be given to prescriptive requirements developed for food safety regulation to ensure that they are practical and can be effectively implemented by the food industry and verified by enforcement authorities.

Critical production parameters, such as time and temperature, applied in food production, and appropriate tools such as predictive models for pathogen inactivation in food production can facilitate an objective assessment of processing requirements to ensure food safety.

Implementation of outcome based food safety requirements, if supported by appropriate implementation tools, can lead to enhanced effectiveness in managing food safety.

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The complete report of this risk analysis can be found on http://www.foodstandards.gov.au/_srcfiles/P251%20UCFM%20FAR.pdf.
Two implementation tools developed as a follow up to this study were not published on the web site of FSANZ, and are available upon request.

Keywords: *Uncooked comminuted fermented meat; Shiga-toxin producing Escherichia coli; log reduction of E. coli; HACCP; food safety programs; risk assessment; food safety regulation.*

COMPETING INTERESTS

Authors have declared that no competing interests exist.