Validation of HACCP in red meat processing

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Introduction

There is an international movement towards outcome-based food safety standards for red meat, especially via the Codex Committee on Meat Hygiene (CCMH) with the Hazard Analysis Critical Control Point (HACCP) concept the tool of choice for hazard management via food safety plans.
In establishing food safety plans there is a requirement that Critical Control Points (CCPs) be validated. The Codex Alimentarius defines validation as *"Obtaining evidence that the elements of the HACCP plan are effective."* (Codex Alimentarius, 1999) This definition is applicable to HACCP, but does not address many of the hygienic measures applied in meat processing (Good Hygienic Practice). More encompassing definitions are required which range from the general *".. obtain evidence to demonstrate the effectiveness of a system of controls"* (Australian Standard for the hygienic production and transportation of meat and meat products for human consumption, 2002) to the specific *"it should be a continuing expert process, assessing and reviewing the scientific and technical content of a HACCP plan to ensure it is effective and complete"* (Brown, 2000). Clearly, validation is the key to a successful outcomes-based approach and validation of food safety systems is likely to become increasingly important as a means of gaining confidence in product safety.

Given the scale of the global red meat trade and the continuing importance of food safety, international alignment on validation is a necessary and desirable process for all stakeholders - consumers, controlling authorities and processing establishments.

In order to explore the concept and to consider examples of validation in the red meat industry, Meat & Livestock Australia (MLA) assembled a panel of international experts in early-2004 to participate in a workshop entitled *"The brave new world of validation"*. A range of validations was considered at the workshop, of which some are presented in the present paper. As well, the rigour with which validation was undertaken is considered.

Types of validation

During the validation workshop, three levels of validation were discussed: validation of a process step (for example, hot water carcase decontamination); validation of a process by reference to process monitoring (for example, *E. coli* levels on caracases) and validation of a regulatory system by reference to process monitoring data collected by establishments under the control of a competent authority.

1. Validating the impact of Good Hygienic Practice

Red meat processing contains a number of constants some of which, in an era of promoting enhanced food safety outcomes, have undergone scrutiny which, to many, might appear heretical:

- Does on-line, post mortem inspection have food safety primacy?
- Can boning (fabrication) rooms operate warmer than 10°C?

- Do knife washing baths need to be 82°C?

The draft Code of Hygienic Practice for Meat (Codex, 2004) has removed prescriptive requirements in favour of a risk-based approach to process requirements utilising scientific data. These red meat processing "sacred cows" were considered at the workshop *"The brave new world of validation"* and may be examined in detail from the workshop proceedings (ijenson@mla.com.au).

The matter of on-line *post mortem* inspection will be reviewed elsewhere at this Congress; as an example of validating in-plant hygiene, the matter of 82°C will be considered.

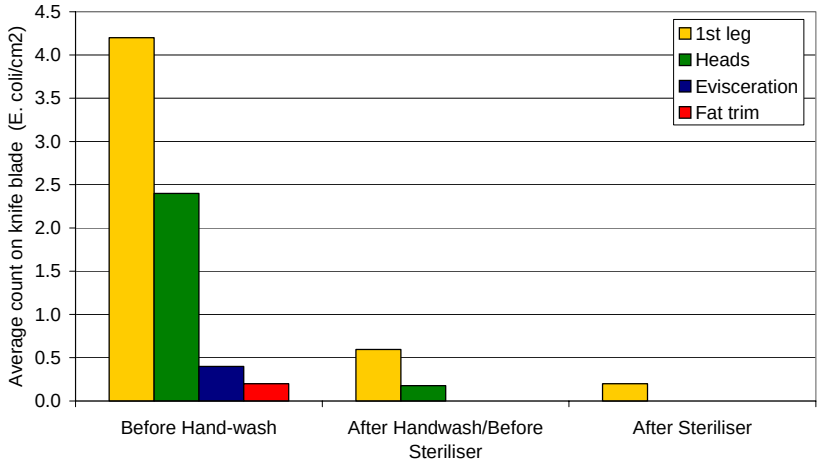
Since the 1960s there have been regulatory requirements in many countries for the use of hot water at not less than 82°C for cleaning of knives and other implements used during slaughter and dressing operations. All Australian red meat establishments are required to have available, at all times, water at a minimum of 82°C. There are potential benefits of using disinfection treatments other than the current requirement of 82°C including:

- Reduced risk of operator injury (scalds etc)
- Reduced hot water consumption, particularly by knife and equipment sterilisers
- Less water, particularly hot water, going to effluent treatment
- Savings in energy costs for heating and reduced greenhouse gas emissions
- Reduced fogging and condensation
- Potential reduction in maintenance requirements

There may also be superior food safety outcomes from using alternative knife cleaning procedures.

Typically over the decades since its inception, knives have been dipped in 82°C during the time that operators move to the next carcase. The thermal process is both brief and variable and plant trials were carried out to assess the effects of hand-wash water and hot water on the numbers of bacteria on knives at specified locations on the slaughter floor. Samples were collected before and after washing under lukewarm hand-wash water, and before and after immersion in the 82°C knife wash (Fig. 1).

Fig 1: *E. coli* levels on operators' knives at various stages of the slaughter/dressing operation



As indicated in Fig 1, knife washing and dipping in 82°C for about 1 second appears to be effective in removing *E. coli* from knives except at the first leg operation, where knife incisions often track through faecal contamination. The data also indicate that for intrinsically cleaner operations, such as fat trimming, washing the knife under warm running water was sufficient to remove detectable *E. coli*.

A series of laboratory trials was carried out to investigate the effectiveness of hot water immersion by application of the following treatments for inactivating test bacteria on knives deliberately coated with a layer of fat or minced meat suspension spiked with *E. coli*:

- Hot water at 72°C, knife immersed for 15 s or 30 s
- Hot water at 75°C, knife immersed for 10 s or 30 s
- Hot water at 82°C, knife immersed for 10 s or 30 s

The results of these processes are presented in Table 1. Immersion of the knives for 30 s at 82°C consistently resulted in reductions of greater than 4.2 $\log_{10}$ *E. coli*/cm^2, and reductions were reliably at least 3.5 $\log_{10}$ units for immersion times of 15 s or longer at 72°C. Reductions after immersion for just 10 s at 75°C were sometimes slightly less.

Table 1: Reduction of *E. coli* on knives after immersion in water for various times and temperatures, using knives contaminated with fat and minced meat

Treatment	Temp (°C)	Time (s)	Mean *E. coli* ($\log_{10}/cm^2$)		Reduction ($\log_{10}/cm^2$)
			Before immersion	After immersion	
Meat matrix					
Hot water	72	15	4.3	0.8	3.5
Hot water	75	10	4.7	1.4	3.3
Hot water	82	1	4.4	1.2	3.2
Hot water	72	30	4.5	<0.3*	4.5*
Hot water	75	30	4.7	<0.3	4.7*
Hot water	82	30	4.2	<0.3	4.2*
Fat matrix					
Hot water	72	15	5.0	1.4	3.6
Hot water	75	10	5.0	0.8	4.2
Hot water	82	1	4.8	1.0	3.8

We could find little or no historical or scientific basis for the use of water no cooler than 82°C. Our work suggests that current procedures (knife dipping for ca 1 second) does not lead to a sanitized knife at all stations along the slaughter/dressing line. However, alternate procedures such as 2-knife immersion at 72°C/15s or 75°C/10s lead to 3-4 log reductions in *E. coli*. The safety of meat might be improved by greater attention to knife sterilization at some points in the process and there may be no negative consequence of applying no sterilization at other points. A performance standard for knife sterilization, such as a 3 $\log_{10}$ reduction in *E. coli* would certainly allow process innovation without affecting product safety, but even greater process innovation might occur, if a requirement relating to the achievement of raw meat microbiological criteria were to be introduced.

The research suggests that alternative knife cleaning equivalent to 82°C/1s include temperature:time combinations in the range 72°C/15s to 75°C/10s. These times are achievable in Australian abattoirs using a 2-knife system where one knife resides in the knife cleaning bath while the other is in use. Given line speeds averaging around 75/hour, residence times of the order 10-15s can easily be accommodated.

These data suggest that knives, depending on where they are used, do not always need to be washed between animals and that 82°C water is not always needed to remove potential pathogens from knives. It is not unlikely that performance criteria for traditional processes could be met by processes utilising judicious modifications to knife sterilising procedures. Equivalent public health outcomes would be achieved, with not insubstantial environmental and occupational health and safety benefits. At this point in time industry has not sought controlling authority approval to implement these procedures, as clarification is obtained on importing country attitudes to potential implementation of these changes.

2. Process Validation using Predictive Microbiology

Traditionally, regulation of meat processing has been based on specific criteria, such as temperature and time for active chilling of meat. More recently, regulations have introduced the concept of performance criteria at the site of microbiological concern. Complementary to this concept has been the development of models which predict growth of target organisms under differing parameters such as temperature, time, pH, lactate and water activity. The Australian meat industry has invested heavily in predictive models (Ross, 1999) and their application across the industry has been summarised by Sumner and Krist (2000).

An example of how predictive models have been used to improve regulation is in the chilling of beef trim from hot boned carcases. Frozen beef trim is used primarily for grinding and patty manufacture and represents Australia's largest volume export commodity, some 3,000,000t being exported, mainly to USA; trim from hot boned carcases represents around 10% of the total export.

From the microbiological viewpoint the chilling of trim in cartons raises concerns because the site of microbiological concern will sometimes be at, or near to, the slowest cooling point of the carton, giving the potential for pathogen growth at this site. Important in chilling (and freezing) cartoned beef trim is the time required for the thermal centre to reach 7°C, a temperature at which growth of enteric pathogens such as *Salmonella* and pathogenic *E. coli* ceases. An early code of practice in Australia stipulated chilling meat to 7°C or colder within 3 hours of slaughter (2 hours from commencement of boning) and then freezing within a further 10 hours, a regime which, unfortunately, could not be achieved by normal cooling practices (Grau and Herbert, 1974).

In 1994 an Australian Quarantine Inspection Service (AQIS) Meat Notice (94/7) introduced some flexibility into the existing arrangements provided the final product remained microbiologically equivalent to conventionally boned meat. This became known as the alternate protocol. However, even with the efficiency of plate freezing, it became apparent that primal cuts (vacuum-packed) could not be chilled to meet the requirements of AQIS Notice 94/7. A scientific panel was convened by Meat & Livestock Australia (MLA) to consider alternative approaches to chilling and freezing

of hot boned meat. The panel considered microbiological data gathered as part of a national baseline study (Phillips *et al.*, 2001) and was satisfied that the hot boning industry was producing bulk-packed frozen meat equivalent to that produced as a result of conventional boning and proposed a revised approach. Under AQIS Notice 2000/06 companies were allowed to operate under trial conditions while their processes were assessed under new predictive microbiological criteria that took into account variability in the production process. The Notice also defined the term Hot Boning Index (HBI).

During the trial, time/temperature recordings were collected from the time of carton closure until the product temperature has fallen below 7^{o}C. It has been clearly shown in the scientific literature that freezing and frozen storage reduces the number of *E. coli* present. Therefore, the HBI should overestimate the potential growth at the thermal centre of the carton. Cartons freeze from the outside, hence bacterial growth is inhibited most quickly in the outer layers. The slowest cooling point in the carton (the thermal centre) represents only a small proportion of the total amount of meat in the carton. Therefore, the HBI for each carton represents a *worst-case example* i.e. potential growth at the slowest-cooling portion of the carton. It provides a more stringent microbiological assessment than would be obtained by normal sampling procedures e.g. microbiological testing of samples drilled aseptically from frozen cartons.

Using the data, a Hot Boning Index (HBI) was calculated for each carton of logged product based on log increase of *E. coli*. The HBI, similar to the Process Hygiene Index (PHI) used in New Zealand, is used to assess the refrigeration processes of hot-boning plants. The HBI is obtained using a predictive microbiology model that estimates the number of generations of *E. coli* at the centre of the carton from time/temperature recordings collected during the refrigeration process. The number of generations can then easily be converted into the increase in the concentration of *E. coli*, expressed in terms of $\log_{10}$.

When each company had surveyed all chilling/freezing regimes, the data (HBIs) were assessed against the following criteria:

- Average Hot Boning Index (HBI) of no more than 1.5 $\log_{10}$
- 80% of the HBIs must be no more than 2.0 $\log_{10}$
- Upper target HBI of no more than 2.5 $\log_{10}$

The model, developed by University of Tasmania (UTAS), is based on 236 growth rate data sets and includes factors additional to those of Herbert and Smith (1980), specifically, pH, lactate and water activity. Further details are given in Ross *et al.* (2003). The equation provides the growth rate in generations per hour (Table 2).

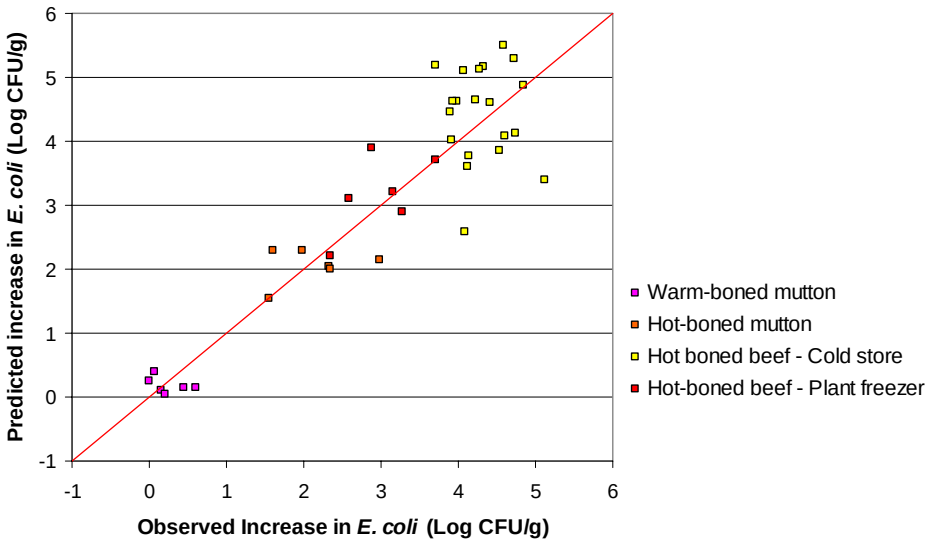
Table 2: Growth rates at various temperatures using the UTAS equation.

Temperature (°C)	Generations/h
35	2.79
30	2.02
25	1.33
20	0.77
10	0.105

The model parameters for pH, a_W and lactate were set based on data for the growth of *E. coli* in bulk-packaged meat. It is impractical for processors to measure these values routinely so average values were used that gave good agreement with observed growth rates. The parameters used were pH 6.5, a_W 0.993 and lactate 51.7 mM. Five generations (1.5 log) are deducted from the predicted potential increase on the basis of evidence regarding the effect of lag phase (Smith, 1985; Ross, 1999).
The UTas model was evaluated against the Pathogen Modelling Program (PMP) and Food MicroModel (FMM) and was particularly good when evaluated for 130 estimates of growth rate in meat with bias and accuracy factors of 0.97 and 1.26, respectively. That this was attributed to the inclusion of a term for lactic acid concentration in the model was demonstrated by poorer performance when the lactate term was removed (bias factor 0.78 and accuracy factor 1.39). A full description of how the performance of the new model was assessed is provided in Mellefont *et al.* (2003).

The model was validated in a number of studies where hot boned meat trim was inoculated with faeces or *E. coli* broth cultures and cooling followed under commercial conditions. A regression plot of the data showing the 95% confidence interval for the line and the 95% predictive interval is shown in Fig 2 (R^2 =0.89).

Fig. 2: Observed increases (log_{10} CFU/g) in coliform bacteria on inoculated surface (faecal suspension) of meat in cartons of boxed beef and sheep meat frozen under commercial conditions plotted against the predicted increase calculated using the University of Tasmania model.



The present example illustrates the rigour which is needed for validation of a new process regulation:

- Examining national baseline microbiological data
- Proposing an alternate regulation for the process
- Formulating a predictive growth model
- Legislating for a trial period of data logging and microbiological monitoring
- Assessing the performance of the model
- Validating the model by in-plant trials

- Assembling all scientific materials in a monograph for review by interested parties

The monograph is available as *Validation of the chilling of hot boned manufacturing meat and primals* from Meat and Livestock Australia (ijenson@mla.com.au)

3. Performance of a national industry

One means of validating that an entire industry operates on a sound basis is to monitor the hygienic quality of its products. Hathaway *et al.* (1999) reported on the National Microbiological Database (NMD) developed by New Zealand authorities. In Australia, the *E. coli* and *Salmonella* Monitoring Program (ESAM) occupies a similar role for export establishments with the Australian Quarantine Inspection Service (AQIS) as their competent authority.

In Tables 3-5 are presented data for the years 2000-03 for *E. coli* count, Total Viable Count (TVC) and prevalence of *Salmonella* on beef carcases produced at export abattoirs in Australia. Sampling aligns with the USA's Pathogen Reduction Program Final Rule.

The data in Table 1 indicate an *E. coli* prevalence around 3% for steers/heifers and 7% for cows/bulls, and a 98th percentile of 0.08 cfu/cm^2 and 0.4 cfu/cm^2, respectively. For both categories mean log TVC/cm^2 is around 1.0 and 98th percentile around log 3.0/cm^2 (Table 2). Over the period 2000-2003, prevalence of *Salmonella* has ranged between 0.26% and 0.43% (Table 3).

Table 1: ESAM data (2000-2003) *E. coli* (cfu/cm^2) on beef carcases

	2000	2001	2002	2003
Number tested	21492	21294	21791	21109
Number (%) positive	1199 (5.6)	976 (4.1)	1065 (4.9)	946 (4.5)
Median	Not detected	Not detected	Not detected	Not detected
80th percentile	Not detected	Not detected	Not detected	Not detected
95th percentile	Not detected	Not detected	Not detected	Not detected
98th percentile	0.2	0.16	0.16	0.17
Maximum	1750	763	416	8300

Table 2: ESAM data (2000-2003) Total Viable Counts (log cfu/cm^2) on beef carcases

	Steers/heifers			
	2000	2001	2002	2003
Number tested	11869	10406	10634	11525
Number (%) positive	10010 (84.3)	8658 (83.2)	8999 (84.6)	10123 (87.8)
Mean	0.90	0.89	0.91	1.08
Standard deviation	1.28	1.29	1.29	0.84
Median	1.15	1.10	1.14	1.08
80th percentile	1.90	1.86	1.83	1.81
95th percentile	2.62	2.59	2.72	2.62
98th percentile	3.02	3.01	3.11	3.01
Maximum	5.65	4.87	4.73	6.00

Table 3: ESAM data (2000-2003) Prevalence of *Salmonella* on beef carcases

	2000	2001	2002	2003
Positives/total (%)	12/2808 (0.43)	12/4583 (0.26)	12/4687 (0.26)	15/4222 (0.35)

In this paper only data for beef carcases are presented; the ESAM program has data for all species exported (bovine, ovine and caprine) together with segmentation into categories (cow/bull, steer/heifer, lamb/sheep, goat skin-on/skin-off). As such it represents a large body of data collected as part of the company Meat Safety Quality Assurance (MSQA) program.

Mandatory accreditation of all laboratories participating in the ESAM program by the National Association of Testing Authorities (NATA) gives confidence in the accuracy of test results. NATA operates to international standards (ISO/ IEC Guide 58:1993, Guide 58 - Calibration and Testing Laboratory Accreditation Systems - General Requirements for Operation and Recognition), All accredited laboratories are required to meet the requirements of ISO.IEC 17025-1999, General Requirements for the Competence of Testing and Calibration Laboratories. All NATA-accredited laboratories are required to participate in an AQIS-NATA proficiency testing programs run in accordance with ISO Guide 43, Development and Operation of Laboratory Proficiency Testing Programs. Participation in these proficiency-testing programs is a prerequisite for ongoing accreditation.

Taken on an industry-wide basis, ESAM represents a validation of the Australian beef slaughter and dressing system

Discussion

Validation in meat processing must engender a high degree of confidence by the competent authority in the safety of the product produced by a processing system both by individual processors and all of the processors operating under that system of control. Since meat processing is generally devoid of process steps that prevent, eliminate or reduce hazards to safe levels, the limited definition of validation, as applied in HACCP, is insufficient; the broader definitions that require validation to collect evidence from multiple sources and assess whether effective control of hazards is demonstrated are more appropriate to meat processing.

The concept of appropriate levels of protection, introduced into international trade through the World Trade Organisation Technical Barriers to Trade agreement requires competent authorities to consider the public health impact of meat and meat products and to consider microbiological limits that are applicable to ensuring the appropriate level of protection. The concept of Food Safety Objective currently being developed by the Codex Committee on Food Hygiene is a useful link between public health and measurable microbiological quality. This leads to a consideration of the impact of process steps on the microbiological outcome and suitable performance criteria for those steps.

In this paper we have presented evidence concerning process steps such as knife sterilization and chilling. The work described here suggests that changes could be made to the traditional “rules of thumb” without an appreciable adverse effect on the microbiological quality or safety of raw meat products. We have also described a monitoring framework that firstly defines the hygienic achievements of traditional processing and provides a standard against which alternative processes may be judged. A challenge for the future will be to link standards of hygienic processing with the achievement of public health goals.

That challenge is an immediate one for the Australian industry. Consistent with the Draft Code of Hygienic Practice for Meat, Australia is currently revising the legislation underpinning the regulation of its export meat trade. In March of 2004, the Australian Government issued "Exposure Draft- Export Control (Meat and Meat Products) Orders" for industry consultation. The Exposure draft proposes to delete the vast majority of prescription from Australia's export meat regulatory regime. The primary focus will instead be of the efficacy of the HACCP based "Approved Arrangement" developed and implemented by the meat export operation. In order to gain approval to produce meat for export, this Arrangement will have to meet specified outcomes contained in the Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption as well as those specified by trading partners.

As opposed to prescriptive regulatory requirements, validation will be the primary tool by which a meat export business will demonstrate to the Competent Authority the effectiveness of the approved arrangement in meeting the outcomes required. It is the view of the Australian industry that this will provide for a much stricter test to be met by Australian meat packers and exporters. It remains relatively straightforward for a meat business to conform with a specified regulatory limit. However, the ability to undertake appropriate validation trials requires a complete understanding of the requisite procedures and processes and how they contribute to the food safety or market access outcome sought. It compels operators to not only have an understanding of "what is required" but to comprehend the reason why a particular procedure is undertaken.

In this environment, the challenge for Competent Authorities is to recognise the increased rigor that this validation process adds to the HACCP based food safety system implemented by the meat business. Furthermore, there is much that relevant meat science disciplines can add to advance existing validation techniques. The challenge for the international meat industry is to continue to foster developments in these areas and encourage their integration into existing operational processes. The outcomes will only continue to improve confidence in red meat food safety.

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