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Review of the Post-mortem Inspection and Disposition Schedules of the Australian Standard 4696

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Abstract

A risk-based review of the Australian Meat Standard (AS 4696-2007) was undertaken to modernise post-mortem inspection and disposition procedures. Risk(based) assessments utilising internationally agreed principles to underpin public health and market access were conducted. In large part these were national studies, conducted in collaboration with industry to provide quantitative data, enabling determination of equivalence of alternatives with the standard. Fourteen risk-based proposals have been approved by the Australian Meat Regulators Group; implementation is underway. Inspection procedures will now reflect improvements in herd and flock health achieved over decades. Results of this work is providing meat safety regulators with information on which to reallocate food safety resources commensurate with risk. The revised procedures also provide an opportunity for better food safety outcomes by reducing contamination of edible tissues. The revised procedures reduce unnecessary waste and maximise use of cuts. The risk-based assessments provide an objective and transparent validation of alternative procedures as a basis for negotiating equivalence recognition for market access. Considerable ongoing communication strategies with key stakeholders is planned to support implementation both domestically and with key export markets. It is recommended that the Project Steering Group be continued to support the coordination of the implementation of alternative procedures.

Executive summary

A risk-based review of the Australian Meat Standard was undertaken to modernise post-mortem inspection and disposition procedures. Risk(based) assessments using internationally agreed principles that underpin public health and market access were conducted to update the Australian domestic standard (AS4696-2007), which serves as the basis for export standards.

Concerns raised by industry risk managers established the Terms of Reference for the review. These included:

1. removing procedures that are no longer necessary due to the improved animal health status of the Australian herd;
2. altering or removing procedures where new knowledge of animal or foodborne disease indicates current risk management procedures are not effective;
3. assessing the effect of cross-contamination arising from current inspection procedures
4. reviewing disposition judgment criteria for total carcase condemnation where appropriate;
5. using alternate risk management procedures either at the processor or elsewhere in the supply chain;
6. identifying procedures that are principally related to product quality rather than food safety that might be transferred to companies' QA systems.

To identify priorities for detailed validation studies of alternative procedures, qualitative risk assessments were conducted for cattle/buffalo and sheep/goats. This entailed conducting:

- an Exposure Assessment utilising existing gross abnormality prevalence data and reviewing this data against overall levels of infections in livestock and carcase/product contamination;
- a qualitative risk rating of hazard:abnormality combinations.

For procedures identified for improvement, current and alternative procedures were compared quantitatively for determination of equivalence by meat regulators.

In practical terms equivalence determination required projects that addressed key data gaps, which included national surveys to determine the types and prevalence of gross abnormalities in a range of tissues/organs and estimating the sensitivity of current and alternative procedures.

The, mostly, national studies, conducted in collaboration with industry provided quantitative data that met the requirements of regulators. All proposals submitted for determination of equivalence addressed whether there was any adverse effect on food safety, wholesomeness and surveillance of animal health (including zoonoses) and welfare.

Fourteen risk-based proposals have been approved by the Australian Meat Regulators Group; implementation is underway. These alternative procedures will be released by the Australian Meat Regulators Group as Guidelines to Schedules 2 and Schedules 3 as a staged process to ensure effective implementation.

In terms of benefits to industry and consumers:

- inspection procedures will now reflect improvements in Australian herd and flock health achieved over decades;
- results have provided meat safety regulators with information on which to reallocate food safety resources commensurate with risk i.e. procedures shown to be ineffective are deleted;

- the revised procedures also provide an opportunity for better food safety outcomes by reducing contamination of edible tissues;
- the revised procedures reduce unnecessary waste and maximise use of cuts, and
- the risk-based assessments provide an objective and transparent validation of alternative procedures as a basis for negotiating equivalence recognition for market access.

Considerable ongoing communication with key stakeholders is required to support implementation both domestically and with key export markets. These include provision of:

- technical support such as fact sheets and training material development;
- meetings with the inspectorate to outline alternatives and the risk-based rationale;
- technical support at industrial meetings;
- presentations of key findings at conferences;
- finalising papers submitted for peer reviewed publication;
- technical support to DAWR in the preparation for equivalence negotiations with trading partners for market access, where needed.

Throughout the project papers have been submitted for peer reviewed publication where findings are considered novel. For other assessments where the findings only bring Australia up to the standards of our contemporaries, the work will remain as research corporation reports. Publication in international journals is seen as assisting negotiation of alternative procedures with key export market regulators. Due to the proportion of meat exported, much of the potential benefits can only eventuate with successful country-to-country recognition of equivalence of the revised procedures.

It is recommended that the Project Steering Group to be continued to support the coordination of the implementation of alternative procedures.

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1 Background

1.1 Introduction

As a leading producer and exporter of beef, sheep and goat meat and a moderate producer of pork, the Australian meat industry maintains advanced food safety and product integrity systems from "paddock-to-plate" to protect public health and maximize export opportunities (APIQ 2017; NVD 2017; Pig Pass 2017; LSA 2017). Continual improvement of these systems warrants periodic major reviews, in this case of post-mortem inspection procedures (Schedule 2) and disposition criteria (Schedule 3) of the Australian Standard 4696 (Anon., 2007).

Traditional organoleptic post-mortem inspection was developed in the late 19th and early 20th century to control important zoonotic diseases such as tuberculosis, taeniasis and trichinosis in Europe and North America when these diseases were relatively prevalent (Federal Meat Inspection Act of 1906; von Ostertag, 1892). In the last 50 years there has been considerable improvement in animal health status in many countries whereby the gross abnormalities found at slaughter are mostly not associated with identified foodborne hazards (Edwards *et al*., 1997; EFSA, 2011; 2013a,b; Hill *et al*., 2014). This improvement is evident in Australia where significant zoonoses (e.g. bovine tuberculosis and *Cysticercus bovis*) have either been eradicated or are rarely seen (Gee, 1986; Sergeant et al., 2017; Meat & Livestock Australia, 2003a,b; Pearse et al.,2010).

Improvements in animal health status have also been accompanied by the recognition that incision and palpation inspection procedures can have a negative effect on meat safety by contaminating edible tissue (Alban *et al*., 2008; EFSA 2011, 2013a,b; Hamilton *et al*., 2002; Nesbakken *et al*., 2003; Pointon et al.,2000; Walker et al., 2000). The resulting negative net effect (i.e. gross abnormalities with human health consequences removed versus contamination increased) was used along with other evidence to justify adoption of routine visual inspection for pigs in European Commission Regulation No 219 (CR, 2014).

For the purposes of this report, the term cross-contamination, is the process by which bacteria or other microorganisms are unintentionally transferred from one substance or object to another (i.e. edible tissue), with harmful effect (i.e. increased risk of consumer exposure). More recently, risk modelling has supported the recognition of the substantial redistribution of *Salmonella* contamination within and between pig carcases resulting from traditional post-mortem inspection (Costa *et al*., 2016).

Efforts to achieve similar reform of post-mortem inspection of cattle, sheep and goats in the European Union based on the risk-based principles has been published (Blagojevic et al., 2012; EFSA 2013ab; Hardstaff et al., 2012; Hill et al., 2013, 2014;). In the United States these same principles have led to the HACCP-Based Inspection Models Project (HIMP) for market hogs approach (FSIS, 2014) in which "establishment employees sort out unacceptable carcasses and parts".

In Australia efforts to reform post-mortem inspection have been active, dating from the 1980s, to align post-mortem inspection procedures with food safety risk. In revising procedures thirty years ago, Murray (1986) promoted the following principles:

- *Differentiation of active and chronic phase of infectious disease whereby chronic lesions are no more than a historical event and should not determine the wholesomeness of meat for human consumption;*
- *Incision of lymph nodes can lead to contamination of edible parts;*

- *Procedures should be reviewed and revised periodically to reflect improvements in animal health status both regionally and nationally resulting from disease eradication, new control tools and practices; and*
- *Recognition and or removal of lesions of limited or no public health significance should be regarded as a commercial concern for processing companies.*

Alternative post-mortem inspection procedures proposed by Murray (1986) were quantitatively validated by McMahon *et al*., (1987). These centred around evaluating the effect of changing from incision of lymph nodes to palpation and from palpation to observation for some conditions. In summary, there were no significant differences found between existing and alternative procedures in relation to residual pathology (McMahon *et al*., 1987). Despite reforms from this early work, Webber *et al*., (2012) cited continued concerns that post-mortem inspection practices were still embedded in a system that was slow to respond to scientific developments that were increasingly providing alternatives with potential to increase consumer protection.

To this effect, these authors note that the core of meat inspection in Australia continues to be largely based on techniques developed in the late 19th and early 20th centuries. In particular Webber et al. (2012) highlight the continuation of outdated procedures and practices such as: (1) failure to fully capture the benefits of eradication of bovine tuberculosis (Gee, 1986; Pearse *et al*., 2009; Sergeant *et al*., 2017;) and (2) the continued treatment of CLA in sheep and goats as a food safety issue instead of a product blemish.

For future development, Webber *et al*., (2012) note that the SPS agreement (WTO 2017) requires regulation only of characteristics relevant to human or animal health and specifies risk assessment as the basis for determining equivalence. Aspects that are of concern for consumer/aesthetic reasons are not identified as being subject to country-country agreements. Reflecting Murray (1986), these authors note risk assessment outputs could then form the basis of allocating inspection resources by identifying procedures that should be conducted by certifying authorities and those that should be fully devolved to the meat company. Continued reform is required to fully capitalize on gains in animal health and those now facilitated by adopting risk assessment principles (CAC, 1999; 2005).

This report details the full results of the review of AS4696:2007 (Anon., 20017).

1.2 Terms of Reference

Reflecting the opportunity for reform enabled by the risk assessment approach, industry consultation with state and federal meat safety risk managers established a willingness to consider equivalence assessments of alternative procedures to Schedules 2 and 3 of the Australian Standard 4696 for Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (Anon., 2007). The terms of reference for the assessment reflect the risk managers' primary concerns for the risk assessors to address. These included:

1. Removing procedures that are no longer necessary due to the improved animal health status of the Australian herd.
2. Altering or removing procedures where new knowledge of animal or foodborne disease indicates current risk management procedures are not effective.
3. Assessing the effect of cross-contamination arising from current inspection procedures
4. Reviewing disposition judgment criteria for total carcase condemnation where appropriate.

5. Using alternate risk management procedures either at the processor or elsewhere in the supply chain.
6. Identifying procedures that are principally related to product quality rather than food safety that might be transferred to companies' QA systems.

It is important to note that in proposing revisions to meat regulation AS4696 in Australia (Anon., 2007), the Australian Meat Regulators Group require validation of an alternative technique (inspection) procedure by demonstrating equivalence with the Standards. For this assessment, this equivalence principle is applied to both food safety and detecting gross abnormalities that only affect product wholesomeness as well as surveillance of animal health (including zoonoses) and welfare.

2 Project Objectives

The technical objectives of the project included:

- Conducting an Exposure Assessment utilising existing abnormality prevalence data together with levels of infection in livestock and carcase/product contamination;
- Conducting a qualitative risk rating of hazard:abnormality combinations;
- Conducting a qualitative risk-impact assessment of alternative;
- Conducting Consequence Assessments, i.e. quantitative hazard-based validation trials of selected alternative arrangements as prioritised by the Steering Committee (effect on risk);
- Modelling effects of alternative procedures especially for low prevalence "wholesomeness" abnormalities;
- Providing additional hazard-based evidence for Controlling Authorities to consider in revising Schedules 2 and 3 of AS 4696;
- Providing evidence for "equivalence" applications to trading partners;
- Obtaining international recognition through peer-reviewed publication of findings.

Regarding the last Objective, the contracted Milestone 12 of V.RBP.0020 specifies preparation of two paper(s) for peer reviewed publication on Kidney enucleation and offal inspection or other as advised by Steering Committee.

3 Methodology

3.1 Project design and implementation

Full details of the design and implementation of the review has been published in full (Pointon et al., 2018 – Supplementary Material 1).

3.1.1 Qualitative risk-based assessment to identify priorities for alternative procedures

The initial work entailed conducting a qualitative risk assessment to compile data in accordance with a risk-based assessment principles (CAC 1999; 2005). These activities cover hazard identification, hazard characterization, exposure assessment and qualitative risk rating.

The methods for each of these activities are fully detailed in the Pointon et al., 2018 (Supplementary Material 1). The main activities undertaken included:

- Updating the hazard identifications for beef, sheep, goats and pigs with an emphasis on the Australian status by consulting with OzFoodNet to extend prior reports (Meat & Livestock Australia, 2003a,b; Pointon *et al*., 2007);
- Characterizing the severity rating of illness due to hazards likely to occur (hazard characterization) (ICMSF 2002);
- Conducting an exposure assessment reviewing Australian data on foodborne hazards in live animals, carcases, offal, lymph nodes, gross abnormalities and carcase condemnations by extending previous reports (Meat & Livestock Australia, 2003a,b; Pointon *et al*., 2007);
- Classifying gross carcase abnormalities listed in AS 4696 as being of foodborne or non-foodborne significance using foregoing information;
- Classifying reasons for total condemnations listed in AS 4696 as being of foodborne or non-foodborne significance using data from the Controlling Authority;
- Reviewing data on inspection as a cause of carcase cross-contamination and identifying issues that may arise from inspection procedures in Schedule 2;
- Evaluating existing gross foodborne or non-foodborne abnormality prevalence and distribution data against current incision/palpation procedures in Schedule;
- Conducting a qualitative risk rating of foodborne hazard:gross abnormality combinations and reasons for carcase condemnation (FSA & Minter Ellison Consulting, 2002; Horchner *et al*., 2006; ICMSF 2002);
- Utilizing the Hazard-Based Decision Tree to specifically address the terms of reference.

3.1.2 Specific risk assessments

Following identification of priorities to revise AS4696 on a risk basis (Table 1) several risk assessment/risk-based assessments were conducted to quantitatively validate the equivalence of alternative procedures with the standard (Anon., 2007). The priorities and types of assessments conducted are listed in Table 1.

The methodology for each of these are available in publications and accepted final reports for the assessments listed in Section 1.1 of this report.

3.1.3 Rationale of risk-based assessment for disposition judgement criteria

More recently, microbiological examination of gross abnormalities, lymph nodes and meat provide additional risk-based information to supplement pathology observations in determining carcase disposition (Kruse *et al*., 2015). This approach not only considers the primary infectious agents that may be causing septicaemia but also foodborne hazards most likely to contaminate edible tissues.

These studies assessed alternative disposition criteria for final carcase disposition judgements for pneumonia, pleurisy and of arthritis cattle, sheep and goats. The disposition criteria included:

- Assessment of the acute (current systemic) versus chronic (localised) nature of gross abnormalities;
- Microbiological testing to determine if totally condemned carcases were septicaemic (actively systemic infection): i.e. is the primary agent or a secondary agent associated with the gross abnormality found in lymph nodes not directly draining the lesion/abnormality and/or edible tissue; and
- Microbiological testing to assess of the presence or absence of food safety hazards in edible tissue.

These principles reflect those expounded by Murray (1986) who noted that assessment of active and chronic phase whereby chronic lesions is no more than a historical event which should not determine the wholesomeness (i.e. suitability CAC 2007) of meat for human consumption.

Such studies of disposition judgement criteria were enabled by atypically high total carcase rate some abattoirs. These assessments inform the appropriateness of trimming multiple chronic abnormalities, interpretation of terms used as "systemic involvement" (Anon., 2007) in the context of the disease continuum from acute/resolving/chronic and their significance in judging food safety status of carcases (Murray 1986; Kruse et al., 2015).

For many diseases the acute/chronic disease framework is already applied in AS4696:2007 Schedule 3 (Anon., 2007). Because of these investigations the Schedule 3 Guideline (Anon.,. 2018b) now extends this acute/chronic framework to the conditions assessed.

3.2 Project steering group

A project steering group, comprised of key stakeholders, was established to ensure the necessary linkages to related work, assessment outputs, direct priorities, oversee risk communication to stakeholders and assessment resourcing i.e. the interface between risk assessors and risk managers (Pointon *et al*., 2006).

The group was comprised of state and federal government food safety officials, red meat and pork industry risk managers and representatives of industry organizations funding this work. This enabled checking alignment of project objectives and rigor with the needs of industry and regulatory risk managers.

3.3 Expert panel

An expert panel was appointed to mostly provide feedback on the methodology within each assessment, assist with or verify by discussion the interpretation of key findings, provide information on current post-mortem inspection procedures and provide recommendations for validation projects. Where data gaps for the prevalence of gross abnormalities of foodborne significance for red meat species existed, these were estimated through informal expert opinion; assumptions made are noted accordingly in supplementary material (Pointon et *al*., 2018a). In selecting the expert panel, the following capabilities were included:

- experience with regulatory reform using Code Risk Assessment guidelines;
- practical and long-standing field experience with meat inspection at the operational and plant management level;
- experience in Controlling Authority roles (including domestic standards management and market access considerations);
- veterinary experience in the field as a plant veterinarian;
- respected authorities in their field;
- experience in using published risk rating methods and publishing outcomes of related studies;
- awareness of the level of evidence required by Controlling Authorities to assess equivalence; statistical and data rigor skills; and
- industry nous with regards to reform in industrially-sensitive areas.

This provided for balanced discussion between relevant stakeholders and scientists familiar with this field.

3.4 Proposals for alternative procedures to the Australian Meat Regulators Group

Proposals of alternative post-mortem inspection procedures were submitted to the Australian Meat Regulators Group (AMRG) for evaluation of equivalence with the Australian meat standard (Table 2).

These proposals not only provided a comparative assessment of food safety, but also suitability and animal health (including zoonoses) and welfare surveillance (Stärk *et al.*, 2014) as required by AMRG.

3.5 Risk Communication

Maintaining open and timely communication with all stakeholders has been a key activity.

Throughout the project several key publications and information sheets have been prepared (i.e. Project Communique, Fact Sheets for the Department of Agriculture and Water Resources (DAWR) "Implementation Pilots") and peer reviewed publications.

Considerable assistance has been provided to AMRG in drafting the alternative procedures into the revised Guidelines for Schedules 2 and 3.

The researchers have been invited contributors at key stakeholder meetings to provide details of the risk-based methods, results and implications for implementation.

3.6 Cost Benefit estimation

An ex-ante estimation of costs and benefits from conducting the review of Australian Standard for *Hygienic Production and Transportation of Meat and Meat Products for Human Consumption* arising from implementation of alternative post-mortem inspection procedures was conducted by a consultant, and the data from this project was used in the estimation.

4 Results

4.1 Qualitative risk assessments

4.1.1 Priorities for quantitative validation

Priorities for risk-based assessments of alternative post-mortem inspection procedures and their rationale are listed in Table 1. Also provided are details of the quantitative validation approach used and how these priorities relate to Terms of Reference set by industry for the review (Section 1.2).

Table 1. List of priority quantitative validation studies of alternative post-mortem inspection and/or disposition judgment procedures for cattle, sheep and goats (Pointon *et al.*, 2018a)

Gross abnormality and disease	Risk-based rationale	TOR	Quantitative validation approach

Cattle			
Tuberculosis[1]	Australian eradication of TB but under-capitalization with regards to inspection	1	Predict level of assurance of eradication using Granuloma surveillance data of past decade
C. bovis[1]	Negligible prevalence, current procedures unlikely to reflect risk	1, 5	Quantitative risk assessment to enable predicting effects of alternative post-mortem inspection procedures
Peri-acute pneumonia in feedlot cattle[1]	Non-foodborne, unexplained increase in total carcase condemnation rate, likely chronic, multiple abnormalities	2, 4	Risk-based evaluation of disposition criteria (microbiology to determine septicaemia, *Salmonella* contamination of meat) to supplement pathology interpretation
Polyarthritis in feedlot cattle[1]	Non-foodborne, increase in total carcase condemnation rate, likely chronic, multiple abnormalities	2, 4	Risk-based evaluation of disposition criteria (microbiology to determine septicaemia, Salmonella contamination of meat) to supplement pathology interpretation
Sheep and Goats			
CLA lesion prevalence and distribution[1]	Non-foodborne, likely prevalence decline, palpating 11 sites, palpation cross-contaminates	2	Determine national prevalence and distribution of multiple lesions within a carcase. Predict cumulative inspection effect for lymph node inspection options. Predict current non-detection rate of CLA gross abnormalities.
CLA alternative inspection procedure[1]	Design alternative arrangement for equivalent food safety and wholesomeness that may utilize company QA interventions.	2,3,6	Desk-top estimation Using data from CLA1 on cumulative inspection effect LN inspection in detecting carcases with multiple lesions. Predict non-detection rate.
Spleen inspection	Abnormalities non-foodborne, likely negligible prevalence, inspection by palpation contaminates. Palpation not done in similar countries	2,3,6	Determine national prevalence of gross abnormalities and compare detection by observation against palpation. Predict sensitivity and proportional non-detection of gross abnormalities.
Kidney enucleation	Similar rationale to Spleens	2	Similar design to Spleen assessment above
Sheep Offal inspection net effect[2]	Palpation for non-foodborne gross abnormalities likely to have negative net effect – hearts selected	3	In-plant evaluation of microbiological effect palpating hearts and net effect using pericarditis as hazard:abnormality combination.

[1] Commissioned by industry as companion studies to Qualitative Risk Assessment priority outputs

In addition, risk-based assessments of criteria used for total carcase disposition judgments were identified in abattoirs experiencing an increased incidence of total carcase condemnations for a specific reason e.g. peri-acute pneumonia and polyarthritis of cattle.

While the disposition judgment projects were enabled by increased rates of specific condemnations at abattoirs, they provided an opportunity for a technical assessment of criteria in use and add extra risk-based information to inform final disposition judgements.

Two companies co-invested with MLA in the conduct of additional projects (P.PPIP.0527, P.PIP.0555) that assessed the criteria used for disposition judgements (Tables 1 and 2).

Desk-top studies of the same conditions was conducted for sheep and goats at the request of AMRG. This arose to assist harmonisation of alternative criteria changes across the major red meat standard in the revised Guideline for Schedule 3.

4.1.2 Hazard Identification

The Hazard Identification (HI) demonstrated *Salmonella* Typhimurium as the most likely hazard to occur in association with fresh meat products in Australia. However, *Salmonella* spp. were found to be a primary or secondary contaminant of a minority of gross abnormalities (Pointon *et al*., 2018a). While *Staphylococcus aureus* is commonly associated with gross abnormalities it was not considered important in judging the food safety effectiveness of post-mortem inspection for beef, sheep, goats and pigs in the review. These animal strains are not recognised as those causing foodborne illness which result from human strains contaminating post-cooked product (i.e. occupational exposure) subjected to temperature abuse enabling toxin build-up (EFSA 2013; Pointon *et al*., 2018a).

The HI confirmed that in the last 50 years there has been considerable improvement in animal health status in Australia whereby most gross abnormalities found at slaughter are not associated with identified foodborne hazards (Pointon *et al*., 2018a). While not directly presenting a public health risk, these gross abnormalities affect suitability. Consequently, demonstrating equivalence of alternative procedures for the detection of non-foodborne gross abnormalities with the Australian meat standard was given similar priority as food safety.

4.1.3 Sensitivity of current and alternative post-mortem inspection procedures

A common data gap found in planning this quantitative validation process was the lack of the sensitivity of current post-mortem inspection procedures (Anon., 2007) against which the alternative procedures could be quantitatively validated. Consequently, for many of these assessments, quantification of the performance of current post-mortem inspection procedures was included to provide a baseline against which the equivalence of the alternative could be determined. For assessing the equivalence of visual only inspection of pigs this entailed using a previous risk-based comparison of visual versus traditional post-mortem inspection (Hamilton et al., 2002) in conjunction with more recent data on prevalence of gross abnormalities (Pointon et al., 2018a).

4.2 Register of projects and approvals

All proposals to AMRG resulted in recommended alternative arrangements being approved (Table 2).

Table 2. Register of approved procedures approved by AMRG

Item No	Matter	Applicant	Decision of AMRG
Schedule 2 – AS 4696			
1	Observation of spleens in Sheep and Goats ***Current:*** *Regulatory compliance action over the recent months has seen field enforcement of mandatory palpation of sheep and goat spleens at post mortem inspection irrespective of whether these spleens are intended for human consumption or removed from the human food chain.* ***Proposed:*** *Observation of spleens of sheep and goats, irrespective of whether spleens are retained for human consumption or not.*	AMIC	Approved in principle, July 2017
2	Reducing incision for *C.bovis* in cattle ***Current****: Incise masticatory muscles (internal and external). Hearts incise internal musculature three to four times in cattle and buffalo.* ***Proposed****: Routinely observe masseters and hearts.* *Current inspection procedures apply if stock have a National Livestock Identification Scheme (NLIS) "alert" indicating lines of animals that are from properties subject to control measures.*	AMIC	Approved in principle, July 2017
3	Alternative procedures for efficient detection of Caseous Lymphadenitis (CLA) lesions in sheep and goats at slaughter ***Current****: Industry-wide problems with Caseous Lymphadenitis (CLA) has been a major issue for the Australian sheep and goat industry for many decades accompanied by significant financial losses to producers. However, with the advent of vaccination and reduced sheep dipping for lice there has been a reduction in prevalence. Despite these improvements in animal health extensive post-mortem inspection procedures remain in the Australian Standard 4696 for inspection of sheep and goats for CLA in Australia (Anon., 2007) especially when compared to other countries (seven sets of lymph nodes versus four sets in the US – John Langbridge pers. comm.).* ***Proposed****: Palpate the four most commonly affected sites of CLA lesions with visual assessment of other sites in sheep and goats.*	AMIC	Approved 3 August 2018
4	Risk-based review of post-mortem inspection of kidneys of sheep and goats ***Current:*** *There is a requirement to routinely observe enucleated kidneys at post-mortem inspection, irrespective of end-use.* ***Proposed:*** *The requirement to observe enucleated kidneys will be risk based and influenced by the end use of the product i.e.* O*bserve enucleated kidneys when for human consumption and observe unenucleated kidneys when not for human consumption.*	AMIC	Approved 3 August 2018
5	TB revisions to reflect export procedures *Procedures updated to reflect those adopted in export establishments in 2011*	Internal AMRG doc	Approved in February 2018

Schedule 3 – AS 4696

Item No	Matter	Applicant	Decision of AMRG
1	Peri-acute Pneumonia of Cattle ***Current**: Peri-acute pneumonia such as severe purulent bronchopneumonia – carcase and all its parts condemned.* ***Proposed**: Delete the term Peri-acute pneumonia in Schedule 3 and replace with more detailed work instructions for carcases where the disposition is uncertain that reflect the alternative procedures i.e. interventions for component gross abnormalities (pleurisy and or peritonitis), re-inspection and test and hold under government supervision, if considered necessary (AS4696:2007 Clause 10.17). Adding partial condemnation as an option will enable equivalent alternative procedures.*	Teys	Approved in principle, July 2017
2	Pilot Risk-Based Evaluation of Disposition Judgement Criteria used for Lot Fed Cattle Totally Condemned for Polyarthritis ***Current**: Disposition judgment criteria for the gross abnormality "Arthritis in cattle" (AS4696 Schedule 3, 3.11). Current procedures may not reflect best practice risk management methodology.* ***Proposed**: Changes to Schedule 3 for "Arthritis" should provide for differentiation of gross abnormalities reflecting stages of disease (i.e. chronic and acute). This would enable appropriate interventions such as trimming multiple chronic lesions, or total condemnation if there are signs of septicaemia or cachexia. This approach is used for other gross abnormalities in Schedule 3, though inconsistently.*	JBS	Approved 3 August 2018
3	Equivalence of alternative disposition judgement criteria for arthritis in Sheep and Goats ***Current**: AS 4696 does not describe carcase disposition for chronic arthritis at multiple sites. AS 4696 does not elaborate on what constitutes systemic effects, however, anecdotal evidence is that inspectors frequently judge that involvement of more than one joint alone indicates systemic involvement with consequent condemnation of the total carcase.* ***Proposed**: It is proposed that acute infectious arthritis is defined as showing evidence of septicaemia, petechial haemorrhage and/or polyserositis, whereupon total carcase condemnation is warranted.* *Chronic cases show no evidence of septicaemia and may have multiple affected joints, which should be trimmed, and the carcase passed accordingly. If showing cachexia total carcase condemnation may be warranted.* *Greater clarity regarding indicators of acute/chronic arthritis is intended to better define criteria for final disposition judgment.*	AMIC	Approved 3 August 2018
4	Equivalence of alternative disposition judgement criteria for pneumonia and pleurisy in Sheep and Goats ***Current**: For many comparable abnormalities in Schedule 3 of AS4696, but not for pneumonia and pleurisy, the standard bases disposition judgment on the criteria of acute or chronic. The acute/chronic framework is intended to better define the number of carcases where there is indecision with regards to final disposition judgment.* ***Proposed**: Risk-based assessment of carcase disposition criteria for sheep and goats with pneumonia and pleurisy by:* *- Describing the bacterial cause(s) of arthritis and whether carcases are septicaemic with those or other agents* *- Quantifying the prevalence of the abnormality at slaughter* *- Quantifying the rate of totally condemned carcases for arthritis/polyarthritis* *- Assessing the food safety of edible tissues from affected carcases at the point of chilling as an indicator of risk* *- Assessing whether remaining infection is localised and active/resolving /chronic to inform final carcase disposition judgement.*	AMIC	Approved 3 August 2018

4.3 Revised Schedules 2 and 3

The alternative procedures summarised in Table 2 are to be published by the Australian Meat Regulators Group as Guidelines for Schedule 2 and 3 (Anon., 2018a,b).

It is anticipated that Schedule 2 guideline will be published in late 2018 followed by Schedule 3 Guideline early in 2019.

4.4 Fact sheets to support implementation

Three fact sheets were prepared for the Department of Agriculture and Water Resources to inform the inspectorate at selected plants participating in an Implementation Pilot. The purpose of the pilots was to identify issues that may arise in the wider roll-out of the alternatives.

Fact sheets for the remaining alternative procedures will be prepared as part on further commissioned work to support implementation by AMRG and DAWR of the revised Schedules.

In addition, a fact sheet explaining the rationale behind alternative disposition judgement criteria has been developed in collaboration with AMRG and DAWR to support implementation and training.

4.5 Publications supporting AS4696 Review

There is now a substantial body of peer reviewed publications underpinning this review.

These include several earlier studies verifying low disease prevalence resulting from improved animal health and eradication of disease. These include:

- Jordan, D., Sentance, C. B., Spooncer, W. F., Balan, J. A., & Morris, S. M. (2012). Inspection of lymph nodes for caseous lymphadenitis and its effect on the density of microbes on sheep carcasses. *Meat Science*, 92(4), 837-840.
- Pearse, B, Langbridge, J, Cobbold R & Glanville R (2009) Current activities add little to food safety. *Fleischwirtschaft* International 24: 46-50.
- Pearse, BHG, Traub, R.J., Davis, A, Cobbold, R. & Vanderlinde, P.B. (2010) Prevalence of *Cysticercus bovis* in Australian cattle. *Australian Veterinary Journal,* 88: 260-262.
- Webber, J. J., Dobrenov, B., Lloyd, J., & Jordan, D. (2012). Meat inspection in the Australian red-meat industries: past, present and future. *Australian Veterinary Journal*, 90(9), 363-369.

There are 5 papers published/submitted as a result of the review where novel information meets publishing criteria.

- Sergeant, E. S. G., Happold, J. and Langstaff, I. (2017). Evaluation of Australian surveillance for freedom from bovine tuberculosis. *Australian Veterinary Journal*, 95(12), 474-479.
- Alban, L., E. Ruttscheid, E., Valeria., C., de Sá, Buholzer, G., P, Madalena Vieira-Pinto, M., Nina Langkabel, N., Meemken, D., **Pointon, A.M., Hamilton, D.H.,** and Abley, M. (2018). Modernization of meat inspection of pigs. The world is on the move towards a more evidence-based type of inspection. *Fleischwirtschaft* international, 2, 8-15.

- Kiermeier, A., Hamilton, D. & Pointon, A. (2018). Quantitative risk assessment for human *T. saginata* infection from consumption of Australian beef. *Microbial Risk Analysis* (submitted June 2018; final edits requested October for publication).
- Pointon, A.M., Hamilton, D.H. and Kiermeier, A. (2018a). Assessment of the post-mortem inspection of beef, sheep, goats and pigs in Australia: Approach and qualitative risk-based results. *Food Control*, 90,222-232.
- Pointon, A.M., Hamilton, D.H. and Kiermeier, A. (2018b). Equivalence of alternative post-mortem inspection procedures for Caseous Lymphadenitis in Australian sheep and goats. *Journal of Food Protection*, (submitted September 2018).

Several investigations that produced evidence to support alternative procedures were nor considered publishable due to these being a "catch-up" to what is recognised and practiced in comparable industries internationally.

A further paper has been drafted for submission after the revised Schedules 2 and 3 are released. This is an advertorial style publication with joint authorship with the Department of Agriculture and Water Resources that targets veterinary regulators of our export markets.

- Allan, S., others, and Pointon, A.M. (2019). Risk-based review of post-mortem inspection procedures and disposition judgement criteria of Australian cattle, sheep, goats and pigs. *Fleischwirtschaft* international (draft only)

In all, these peer reviewed publications target areas of major change where equivalence agreements with trading partners will be required to maintain market access to deliver maximum benefit to industry.

4.6 Technical meetings

The researchers attended many meetings and conferences held by stakeholders to outline the risk-based rationale of the review, provide updates on results, assist with official consideration of proposals, draft revised Schedules 2 and 3 Guidelines and to support implementation.

4.7 Project Steering Group

The Project Steering Group met on 6 occasions to ensure all stakeholders were kept abreast of progress and issues arising, especially where their guidance was needed.

The Australian Meat Industry Council was particularly helpful in recruiting establishments to participate in projects and identify priorities for additional assessments.

As the project has progressed, the role of the Steering Group has shifted to coordination of implementation by involved stakeholders.

This has seen addition of MINTRAC as an important part of the planned roll-out.

More recently a Gantt Chart integrating activities of key stakeholders has been requested and developed to assist efficient and effective implementation of the alternatives from which benefits to industry will flow.

4.8 Risk Communication

Examples of recent communication activities are shown in Table 3.

Table 3. Communication Activities and Status (February – October 2018)

Date	Activity	Status
Feb	Drafted internal AMRG paper on TB alternative procedures	Approved by AMRG Feb
Feb	Drafted and submitted two proposals on Alternative Procedures for Pneumonia/Pleurisy and Arthritis for Sheep and Goats – AMIC proposals to AMRG	AMRG requested resubmission with "new" AMRG Proposal Form
March	Half day presentation on AS4696 Review – Principles and Results to FOMs and ATMs in Canberra	Completed
March	Prepared paper on Residual Red Meat Palpation for Project Steering Group meeting	Tabled at Project Steering Group meeting
March	Attended Project Steering Group meeting, Canberra	Ongoing activity
May	Prepared and submitted Cost:Benefit estimation of red meat alternative procedures	Accepted by MLA
June	Resubmitted 5 red meat and 1 pork proposal with accompanying AMRG Proposal Form for Alternative Techniques – AMIC, JBS and APL proposals to AMRG	Completed
July	Prepared first drafts of three Fact Sheets for DAWR Implementation Pilots	Completed
July	Drafted full revisions of Schedules 2 & 3 assuming all approved by AMRG – for consideration at 3 Aug meeting of AMRG in Perth	Completed and approved by AMRG
July	Responding to referee comments for manuscript - Quantitative Risk Assessment for Human *Taenia saginata* Infection from consumption of Australian Beef.	Resubmitted to *Microbial Risk Analysis* Awaiting editor review
July	Drafted "AMRG Proposal Forms" for the seven proposals approved prior to August 2018 to support development of implementation Fact Sheets	Completed
August	Participated in AMRG teleconference considering resubmissions and fully revised Schedules 2 & 3	Completed
August	Prepared Fact Sheet for AMRG - *Australian Standard Alternative Equivalent Procedure: Rationale for Schedule 3 Alternative Disposition Judgement Criteria.*	Completed
September	Two-day drafting meeting with DAWR and AMRG to finalise Schedule 2 Guideline documentation, plan Schedule 3 Guideline, review Implementation Pilots, plan Fact Sheets for all approved alternatives, develop a coordinated implementation plan.	Schedule 2 Guideline completed. Defined ongoing workplan for AMRG, DAWR and MLA.

4.9 Benefits to industry

Data from this project, and opinions arising from experience gained during the project were contributed to an ex-ante cost:benefit estimation conducted by another consultant.

Benefits are expected to arise from from value-added to product, reduced inspection costs and reduced wastage

Consequential costs of implementation not calculated include training and export access negotiations.

5 Discussion

In summary, the stages required to effect regulatory change follows the risk analysis framework where risk managers initially articulate risk management questions for the risk assessors to address. This final report covers these two aspects in detail.

The next step is for risk managers, in this case the Australian Meat Regulators Group representing state and federal jurisdictions, to evaluate the equivalence of quantitative validation of alternative procedures with the standard. This has occurred in response to formal proposals based on the risk assessments being submitted by industry to AMRG.

The final step is that of risk communication with a broad range of stakeholders. This report recommends priority communication activities for consideration to achieve effective and efficient implementation of alterative procedures.

5.1 Industry Outcomes and Technical Objectives

5.1.1 Industry Outcomes sought - Terms of Reference

Approved alternative procedures aligned with its corresponding Terms of Reference (i.e. industry outcomes sought) are listed in Table 1. When taken together these indicate there was substantial opportunity, based on risk, to modernise the standard.

Removing procedures that are no longer necessary due to the improved animal health status of the Australian herd:

- bovine tuberculosis and beef measles.

Altering or removing procedures where new knowledge of animal or foodborne disease indicates current risk management procedures are not effective:

- inspection for caseous lymphadenitis of sheep and goats;
- spleen and kidney inspection of sheep and goats; and
- revised disposition criteria for polyarthritis and peri-acute pneumonia for these species.

Assessing the effect of cross-contamination arising from current inspection procedures:

- sheep offal inspection net effect.

Reviewing disposition judgment criteria for total carcase condemnation where appropriate:

- peri-acute pneumonia of cattle/ buffalo and sheep/goats;
- polyarthritis of cattle/ buffalo and sheep/goats.

Using alternate risk management procedures either at the processor or elsewhere in the supply chain:

- Onchocerciasis project not impacting AS4696:2007.

Identifying procedures that are principally related to product quality rather than food safety that might be transferred to companies' QA systems:

- spleen and kidney inspection of sheep and goats provide opportunity for this type of reform.

5.1.2 Technical objectives

The technical objectives to achieve the industry outcomes specified above included:

- Conducting an Exposure Assessment utilising existing abnormality prevalence data together with levels of infection in livestock and carcase/product contamination;
- Conducting a qualitative risk rating of hazard:abnormality combinations;
- Conducting a qualitative risk-impact assessment of alternative procedures and arrangements;
- Conducting Consequence Assessments, i.e. quantitative hazard-based validation trials of selected alternative procedures as prioritised by the Steering Committee (effect on risk);
- Modelling effects of alternative procedures especially for low prevalence "wholesomeness" abnormalities;
- Providing additional hazard-based evidence for Controlling Authorities to consider in revising Schedules 2 and 3 of AS 4696.

These technical objectives have all been achieved either in the qualitative risk assessment (Pointon et al., 2018a) or in the quantitative assessments of alternative procedures that underpinned the proposals to AMRG listed in Table 2.

5.2 Communication of findings to stakeholders

5.2.1 Implementation Pilots

DAWR conducted three pilot trials to identify issues that might arise in the roll-out of the alternative procedures in export licenced plants. This included alternatives for spleens of sheep and goats and two disposition judgement criteria alternatives for pork ; one being peri-acute pneumonia which will apply to cattle/buffalo and sheep and goats.

Fact Sheets detailing the rationale and specific changes were prepared for plant vets and inspectors by the Principal Investigator and the Veterinary Technical Manager DAWR. Feedback was that the pilot trial of revised procedures was well understood and implemented successfully. For spleens difficulty arose when not presented for immediate observation. Presentation of spleens for observation of by industry will be important for full benefit to be obtained.

5.2.2 Peer reviewed publications

The following papers for peer reviewed publications have been prepared as specified for this Final Report (Milestone 12). The first on Caseous Lymphadenitis has been submitted and while the latter is intended to be submitted after AMRG has released Guidelines for Schedules 2 and 3. The latter paper will also require authorisation from DAWR especially if Dr Sam Allan is the first author.

Pointon, A.M., Hamilton, D.H. and Kiermeier, A. (2018b). Equivalence of alternative post-mortem inspection procedures for Caseous Lymphadenitis in Australian sheep and goats. Journal of Food Protection, (submitted September 2018).

Samantha Allan, Andrew Pointon and others (2019). Risk-based review of post-mortem inspection procedures and disposition judgement criteria of Australian cattle, sheep, goats and pigs. *Fleischwirtschaft* international (draft only)

5.2.3 Australian Meat Regulators Group – regulatory approval

AMRG has decided to progress the implementation of alternative procedures in a staged manner. Schedule 2 alternative inspection procedures are considered straight forward to implement. A Schedule 2 Guideline has been prepared for consideration by AMRG in November 2018. Fact Sheets have been prepared for all the alternative procedures detailed in Table 2. Fact Sheets have also been prepared for pork carcase alternatives in Schedule 2 to support coordinated release. As each state jurisdiction will provide the Guideline to all plants licenced in each jurisdiction, all export registered plants will be advised in this manner.

As Schedule 3 alternatives relate to revised disposition criteria, AMRG has requested a *Fact Sheet: Schedule 3 Alternative Explained* to support implementation. This material and Fact Sheets for each of the red meat (Table 2) alternatives have been prepared to support implementation and support any training required. A Schedule 3 Guideline can be extracted from the full draft of alternative procedures approved by AMRG.

5.2.4 Export market access – equivalence of alternative procedures

Due to the proportion of meat exported, much of the potential benefits can only eventuate with successful country-to-country recognition of equivalence of the revised procedures. Publication in international journals is seen as assisting negotiation of alternative procedures with key export market regulators. Consequently, throughout the project, papers have been submitted for peer reviewed publication where findings are considered novel. In this regard a paper has been drafted outlining the application of risk principles in this review. This targets veterinary regulators and summarises the breadth of work undertaken and published (section 4.5).

Ultimately, however, the ability to fully implement alternative procedures rests on acceptance of alternative procedures by regulators of our export markets. The responsibility for negotiating this outcome is the jurisdictional responsibility of the Department of Agriculture and Water Resources. It remains an active action on the agenda of the Project Steering Group. It is most likely that some changes will only require notification i.e. where the changes bring practices up to that accepted and applied internationally. Others may require negotiation of equivalence agreements e.g. *C. bovis*.

5.3 Key factors underpinning project implementation

The critical role played by industry cannot be under-estimated. As risk assessment principles are based on consumer exposure to foodborne hazards, it is essential to have data that reflects the prevalence and variation in animal disease occurrence and expression nationally. The same applies to gross abnormalities that only affect wholesomeness.

Acquisition of this data is generally beyond the resources and capability of a research team due to the large numbers that need to be surveyed across the major production zones for extended periods.

Company and inspection personnel followed SOPs, case definitions, sampling protocols and data recording sheets with great attention to detail, without which the quantitative assessments could not be conducted.

6 Conclusions/recommendations

Risk-based assessments of post-mortem inspection and of disposition judgement criteria has resulted in a significant number of alternative procedures being approved for both Schedules 2 and 3 of AS4696:2007.

While the timing of implementation of Guidelines for Schedule 2 and 3 remains with the Controlling Authorities which constitute AMRG, there remain many activities that are needed to support implementation. These include provision of:

- technical support to preparation of Fact Sheets for Schedule 2 and 3 Guidelines:
- technical support to training material development;
- key meetings with the inspectorate to outline alternatives and the risk-based rationale;
- technical support at industrial meetings;
- presentations of key findings at conferences;
- finalising papers submitted for peer reviewed publication;
- technical support to DAWR in the preparation of equivalence negotiations with trading partners for market access, where needed.

The latter activity of DAWR is critical to ensure potential benefits from the work are fully realised.

Further research on remaining palpation procedures of cattle and sheep/goats has been prepared for consideration by the Project Steering Group.

It is recommended that the Project Steering Group to be continued to support the coordination of the implementation of alternative procedures. The immediate activities relate to coordination of release of the Guidelines with supporting material and associated training.

7 Key messages

Post-mortem inspection and disposition judgement criteria in the Australia meat safety standard have been modernised.

The alternative procedures were validated by undertaking risk-based principles and methodologies agreed internationally to underpin public health and market access.

Inspection procedures will now reflect improvements in herd and flock health achieved over decades.

Results of this work provide meat safety regulators with information on which to reallocate food safety resources commensurate with risk.

The revised procedures also provide an opportunity for better food safety outcomes by reducing contamination of edible tissues.

The risk-based assessments provide a transparent and objective validation of alternative procedures as a basis for negotiating equivalence recognition for market access.

The revised procedures reduce unnecessary waste and maximise use of cuts.

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