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AUSTRALIAN Pork

Risk-based review of post-mortem inspection of kidneys of pigs

Final Report
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Executive Summary

The Australian Meat Regulators Group (AMRG) is supportive of a review of the post-mortem procedures and dispositions as listed in Schedules (2 and 3) in the current (pork) meat Australian Standard 4696 (Anon, 2007).

The final report of APL Project 2015/023, reviewing post-mortem inspection and disposition judgment, was presented to the Pork Processor Referral Group (PPRG) in June 2017. It was reported that the AMRG had approved, in principle, the move to routine visual post-mortem inspection, and that the AMRG was developing an implementation process for alternative procedures.

Following the advice that regulatory change is imminent, PPRG members requested that further work be undertaken to validate the equivalence of observing unenucleated kidneys as an alternative inspection procedure for kidneys.

The key principles of the AMRG in the assessment of equivalence of alternative post-mortem procedures with the Standard include:

- Does the proposal result in a better/equivalent food safety outcome?
- Is the science risk-based and representative of the Australian situation, i.e. reflecting consumer exposure, animal health status, regional production and seasonal influences (as appropriate)?
- Does the proposal address meat wholesomeness?
- Do the proposed alternative post-mortem inspection procedures affect judgement of carcase disposition?
- Do the proposed alternative post-mortem inspection procedures affect animal health and welfare surveillance, including zoonoses?

Through discussions with risk managers the issues that justify the assessment are:

- Gross abnormalities of kidneys are likely to be of limited food safety risk
- Severe nephritis is indicative of leptospirosis as an occupational zoonotic risk to producers, transport drivers and abattoir personnel
- Detection of gross abnormalities of kidneys is unlikely to inform carcase disposition that is not available otherwise
- Current inspection procedures add opportunity for cross contamination with microbial pathogens due to handling of kidneys
- Enucleating kidneys is a labour-intensive activity, requiring up to two operators (depending on chain speed) solely for this activity
- Kidneys are not often saved for human consumption.

Under alternative inspection procedures approved by the AMRG there will be no requirement to routinely palpate enucleated kidneys at post-mortem inspection, irrespective of end-use.

The question raised by members of the PPRG is: Can this alternative inspection procedure of observing pig kidneys be extended to observing unenucleated kidneys?

The project assesses whether alternative inspection procedures for pig kidneys can provide equivalence with the standard (AS4696:2007). The technical objectives of the project are to:

- Determine the foodborne hazard and zoonotic significance of gross abnormalities of pig kidneys
- Quantify the industry prevalence of gross abnormalities of kidneys, including a breakdown of prevalence by type of gross abnormality
- Quantify the role of gross abnormalities of kidneys in informing carcase disposition judgment
- Predict the effect of inspecting unenucleated kidneys by observation.

A national snapshot prevalence survey of one week's production through the seven major abattoirs was conducted. This aimed to provide the prevalence of gross kidney abnormalities in approximately 85,000 pigs. Carcases were examined over one week/abattoir to encompass pigs from all herd sizes and production systems on a proportional basis.

Inspection/recording of the types and prevalence of gross abnormality was undertaken by 'Certified Level 3 Meat Inspectors', authorised as Australian Government Authorised Officers i.e. Certified Australian Government Authorised Meat Inspectors with Certificate 3 and/or 4 in Meat Safety.

The prevalence of gross abnormalities of kidneys was 6.43% of 84,047 pigs inspected. Only 0.014% of 84,047 pigs had gross abnormalities of food safety significance (1.4/10,000 carcases). Of the 5,403 pigs with gross abnormalities, 65.0% had cysts. Nephritis was detected in 2.0% of 84,047 pigs with 0.49% of 84,047 pigs having Grade 2 nephritis. Generalised conditions (tumour, uraemia, anaemia) were detected in 0.04% of 84,047 pigs. For pigs inspected by observation of unenucleated kidneys the estimated increase in non-detection rates on a /10,000 carcase basis is estimated to be substantial for Grade 1 nephritis and moderate for grade 2 nephritis and cysts.

In terms of significance for carcase disposition judgement, a total of 27 of 84,047 inspected pigs with kidney gross abnormalities were totally condemned (0.032%). Of these, five carcases were condemned for food safety reasons, these being septicaemia (four) and pyaemia (one) (i.e. 0.6/10,000 carcases). Another five carcases were condemned for reasons unrelated to kidney lesions detected in that carcase, i.e. pigs condemned due to arthritis (four) and pyrexia (one) that had cysts. Kidney lesions alone may have been a major reason in one of the 27 total condemnations i.e. a tumour that may have signalled metastatic spread.

On an individual carcase basis at the point of post-mortem inspection, it is estimated that the specificity of nephritis Grade 2 gross abnormalities for leptospirosis infection is 95.7%.

* Based on estimated herd sensitivity (SeH) and specificity (SpH) estimates at optimum cut-off values for positive Grade 2 lesions, detected by observing unenucleated kidneys, perform surprisingly well as a surveillance tool for herd leptospirosis infection.

Implications and recommendations arising from the assessment follow.

1.1 Routine Inspection

Key findings that underpin the equivalence of alternative post-mortem inspection procedures include:

- Procedures need to reflect product end-use i.e. kidneys retained for human consumption and those retained for animal food

- There is a negligible prevalence of gross abnormalities of food safety risk to consumers
- Observing unenucleated kidneys is estimated to have a negligible effect on nondetection rate for gross abnormalities of food safety significance, however, wholesomeness would be adversely affected for some gross abnormalities
- Kidney gross abnormalities have negligible value in determining the final carcase disposition judgement
- Kidneys with Grade 2 nephritis are commonly infected with leptospirosis
- Observing unenucleated kidneys will reduce zoonotic risk to abattoir personnel
- Observing unenucleated kidneys remains a useful surveillance tool for identifying herds likely to be infected with leptospirosis.

Recommendation

Proposed alternative post-mortem inspection procedures for consideration by the AMRG follows.

Table 1 Current and proposed alternative post-mortem inspection procedures for Schedule 2 AS4696:2007

Current (AS4696: Schedule 2)	
Kidney (enucleated)	Palpate
Alternative post-mortem inspection procedures	
Kidney not for human consumption	Observe unenucleated kidneys
Kidney for human consumption	Observe enucleated kidneys

Observing kidneys is consistent with previous AMRG approval for routine visual inspection of pigs based on the final report of APL Project 2015/023. That decision also provides for palpation if considered suspect or if needed to inform carcase disposition judgement.

1.2 Location of inspection

Issue

As kidneys have negligible value for determining final carcase disposition, the option arising for those retained for human consumption is enucleating and inspecting (by observation as above) in the offal room.

Recommendation

That kidneys retained for human consumption may be inspected by observation of enucleated kidneys at sites other than the slaughter-floor e.g. offal room.

1.3 Animal Food

In consideration of the use of unenucleated kidneys for animal food, all hazards associated with gross abnormalities of pig kidneys identified would be inactivated by routine heat-treatment when used for animal food.

Recommendation

That the disposition applied to unenucleated kidneys inspected by observation allow these to be recovered for animal food under AS4696: 10.12 (a) (iii).

1.4 Effect of observing unenucleated kidneys on animal health (zoonosis) surveillance

As observing un-enucleated kidneys Grade 2 kidney lesions performs surprisingly well as a test for herd leptospirosis infection, the proposed alternative post-mortem inspection procedures remain a useful herd surveillance tool for leptospirosis.

Recommendation

Nephritis (Grade 2 especially) should be included in the producer feedback project to foster greater control of leptospirosis and mitigate the zoonotic risk of farm, transport and abattoir personnel.

1.5 Submission for determination of equivalence by the AMRG

This report has been drafted to address the requirements of proposals for consideration of equivalence with the Standard (AS4696).

Recommendation

That this report be submitted by APL to the AMRG for consideration in time to be included in Version 1 of Schedules 2 and 4 in early 2018.

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2. Background to Research

2.1 Post-mortem Inspection Review Agenda and Consultation

The Australian Meat Regulators Group (AMRG) are supportive of a review of the post-mortem procedures and dispositions as listed in Schedules (2 and 3) in the current (pork) meat Australian Standard 4696 (Anon 2007). As parallel work is being conducted by the red meat industry, the Australian pork industry is presented with an opportunity to conduct a risk-based review of regulatory arrangements (CAC, 2005).

The AMRG has requested that the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ) Alternative Procedures Protocol (Meat Research Corporation, 1997) be utilised as guidance for the preparation of submissions.

The key principle in that guideline that applies in this instance is:
Validating an alternative technique procedure to demonstrate equivalence with the Standards.

The final report of APL Project 2015/023 reviewing post-mortem inspection and disposition judgment was presented to the Pork Processor Referral Group (PPRG) in June 2017. It was reported that the AMRG had approved in principle the move to routine visual post-mortem inspection and that AMRG was developing an implementation process for the changes.

Following the advice that regulatory change is imminent, PPRG members requested that further work be undertaken to validate the equivalence of observing unenucleated kidneys as an alternative inspection procedure.

2.2 Terms of Reference

Current post-mortem inspection procedures detailed in Schedule 2 Table 2 (Anon, 2007) require pig kidneys to be palpated after enucleation from the capsule of the kidney, irrespective of whether they are retained for human consumption.

The assessment requested is to evaluate the equivalence of observation of unenucleated kidneys with the Standard (A4696:2007).

The key principles followed in the assessment of equivalence of alternative post-mortem procedures with the Standard include:

- Does the proposal result in a better/equivalent food safety outcome?
- Is the science risk-based and representative of the Australian situation, i.e. reflecting consumer exposure, animal health status, regional production and seasonal influences (as appropriate)?
- Does the proposal address meat wholesomeness?
- Do the proposed alternative post-mortem inspection procedures affect judgement of carcase disposition?
- Do the proposed alternative post-mortem inspection procedures affect animal health and welfare surveillance, including zoonoses?

2.3 International Developments

Reform of post-mortem inspection and disposition judgment is continuing internationally, largely enabled by the Code of Hygienic Practice for Meat (CAC, 2005).

Also of importance in this regard is the Sanitary and Phytosanitary Agreement (SPS) that requires regulation only of characteristics relevant to human or animal health, and specifies risk assessment as the basis for determining food safety equivalence (WTO, 2017). Aspects that are of concern for consumer/aesthetic reasons are not identified as being subject to country-country agreements. Risk assessment outputs are now used to 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.

Risk assessment also enables consideration of the effect of any alternative procedures on surveillance of animal health (including zoonoses) and welfare surveillance (EFSA, 2011; Stark et al., 2014). This reflects the Code of Hygienic Practice for Meat (CAC, 2005), where at the national level the activities of the Competent Authority have jurisdiction at the slaughterhouse that very often serve animal health as well as public health objectives. This applies to ante- and post-mortem inspection where the slaughterhouse is a key point in animal health surveillance, including zoonoses.

Regardless of jurisdictional arrangements, it is important that this duality of functions is recognised and relevant public health and animal health activities remain integrated (WTO, 2017).

Considerable effort in applying risk assessment principles to reform post-mortem inspection has been undertaken recently in Europe and Noth America. Opportunity for reform has arisen from a combination of improvements in animal health and the recognition that incision and palpation inspection procedures can have a negative effect by cross-contaminating carcases (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 of traditional post-mortem inspection (i.e. hazard:abnormalities combinations removed versus microbial contamination added) was used along with other evidence to justify adoption of routine visual inspection for pigs in European Commission Regulation No 219 (CR, 2014).

In the United States these same principles have led to the Evaluation of HACCP-Based Inspection Models Project (HIMP) for Market Hogs approach (FSIS, 2014) in which ‘establishment employees sort out unacceptable carcases and parts’.

3. Objectives of the Research Project

3.1 Need

Issues identified through discussions with risk managers that justify a risk-based assessment are:

- Gross abnormalities of kidneys are likely to be of limited food safety risk
- Severe nephritis is indicative of leptospirosis as an occupational zoonotic risk to producers, transport drivers and abattoir personnel
- Detection of gross abnormalities of kidneys is unlikely to inform carcase disposition that is not available otherwise
- Current inspection procedures add opportunity for cross contamination with microbial pathogens due to handling of kidneys
- Enucleating kidneys is a labour-intensive activity, requiring up to two operators (depending on chain speed) solely for this activity
- Kidneys are not often saved for human consumption.

Under alternative inspection procedures approved by the AMRG (Pointon et al., 2017) there will be no requirement to routinely palpate enucleated kidneys at post-mortem inspection, irrespective of end-use. This is largely in recognition that traditional inspection is likely to be microbiologically counter-productive resulting in a poorer overall food safety outcome (EFSA, 2011; Pointon et al., 2017). In that decision, the AMRG has allowed for palpation and incision of tissues when indicated by other gross abnormalities of that carcase or herd health history.

The question raised by members of the PPRG is: Can this alternative inspection procedure of observing pig kidneys be extended to observing unenucleated kidneys?

3.2 Objectives

The objective of the project is to assess whether alternative inspection procedures for pig kidneys can provide equivalence with the Standard (AS4696:2007).

The technical objectives of this project are to:

- Determine the foodborne hazard and zoonotic significance of gross abnormalities of pig kidneys
- Quantify the industry prevalence of gross abnormalities of kidneys, including a breakdown of prevalence by type of gross abnormality
- Quantify the role of gross abnormalities of kidneys in informing carcase disposition judgment
- Predict the effect of inspecting unenucleated kidneys by observation.

These data will enable the AMRG to consider the equivalence of alternative post-mortem inspection procedures for pig kidneys.

4. Introductory Technical Information

A key consideration in the design of this equivalence assessment is that of product end-use. For pig kidneys this includes retaining for human consumption and use in animal food (AS4696:2007 Interpretation).

In this context, a survey of the seven export listed abattoirs was conducted to establish the proportion retained as edible tissue. Data shown in Table 1 indicates the bulk are not retained for human consumption, but that a high proportion may be retained where markets exist.

Abattoir	% retained for human consumption
1	75%
2	4%
3	0%
4	2-15%
5	16%
6	No response
7	10%

For use as Animal Food the Australian Standard 4696 (Anon 2007) states:

1.3 Interpretation

Animal food means:

a. A part of any animal or a meat product to which a disposition has been applied enabling it to be recovered for animal food

10. Post-mortem inspection and disposition

10.12 one of the following dispositions is applied

a. for carcases and carcase parts:

iii. unfit for human consumption and may be recovered for animal food.

5. Research Methodology

5.1 Risk-based approach

In summary, Codex risk assessment guidelines applied (CAC, 1999, 2005; EFSA, 2013a,b) include:

- Being conducted on a national basis to reflect the variation that might occur due to regional production system and/or seasonal differences (where applicable)
- Reviewing the likely gross abnormalities and their foodborne significance
- Predicting the effect on alternative procedures delivering equivalent or better food safety outcomes
- Quantifying any effect on wholesomeness
- Quantifying any effect on animal health, including zoonoses, surveillance.
- Determining the quantitative effectiveness of alternative procedures on a national basis.

5.2 Hazard identification

Foodborne outbreaks attributed to consumption of pig kidneys has been included in a search of the OzFoodNet outbreak database (Pointon et al., 2017).

To classify these abnormalities as being of foodborne or non-foodborne significance (Table 1), a desk-top review of key text books on diseases and pathology of pigs was utilised in conjunction with specific literature reviews (Pointon et al., 2017).

5.3 Hazard Characterisation

For the purposes of this review, the risk rating criteria used for rating the severity of public health foodborne infection consequences are those published by ICMSF (2002).
The criteria used include:

1A Severe hazard for general population: life threatening or substantial chronic sequelae or long duration
1B Severe for restricted populations: life threatening
C Serious, incapacitating but not life threatening; sequelae infrequent; moderate duration
D Moderate, not usually life threatening; no sequelae; normally short duration; symptoms are self-limiting; can be severe discomfort.

5.4 Exposure Assessment: Design and Methods

A national snapshot prevalence survey of one week's production through the seven major abattoirs was conducted. This aimed to provide the prevalence of gross kidney abnormalities in approximately 85,000 pigs.

Gross abnormalities were recorded in a data recording sheet by all abattoirs (Appendix 1). Of these, only nephritis, due to leptospirosis in outdoor pig production systems, may have a seasonal occurrence due to pigs having access to contaminated water. The effect of season is uncertain; both wallows in summer and pools of water in winter may pose a source of exposure of pigs to infection. However, for convenience, pig carcases were only examined in spring.

For carcases where one or both kidneys show gross abnormalities, the final carcase disposition was recorded. Where the carcase was totally condemned, the reason for condemnation was recorded. Carcases were examined over one week/abattoir to encompass pigs from all herd sizes and production systems on a proportional basis.

Inspection/recording of the types and prevalence of gross abnormality was undertaken by 'Certified Level 3 Meat Inspectors' authorised as Australian Government Authorised Officers i.e. Certified Australian Government Authorised Meat Inspectors with Certificate 3 and/or 4 in Meat Safety.

5.5 Data Analysis

5.5.1 Estimating the difference in detection rates of observing unenucleated kidneys versus palpating enucleated kidneys

The number of carcases with affected kidneys (uni- or bilateral) for each abnormality were tabulated and the detection rate, as a percentage and per 10,000 carcases inspected, was calculated for each abnormality. In addition, the non-detection rate per 10,000 carcases inspected was calculated, using a sensitivity of detection of Se = 95%, as follows:

Non-detection rate = Detection Rate × (1/Se – 1)

Due to the very low prevalence of gross abnormalities of kidneys, including those of foodborne significance, quantifying the effect of alternative procedures (Observation versus Palpation) on non-detection is almost logistically impossible. Consequently, the effect of implementing alternative procedures is estimated as an initial assessment.

For this purpose, estimation of the non-detection rate under the unenucleated/observed alternative procedures was calculated using revised sensitivities (Table 4), explained in the following paragraph, and are in addition to the existing non-detection rate of enucleation/palpation.

Based on the authors' experience (Pointon et al 1999) the presumed proportion of enucleated and palpated positive kidneys that were positive when inspected unenucleated and by observation was estimated on an abnormality basis (Table 4). Those typified by holes (cysts) or lumps (tumour, abscess) are considered easily detected by observation and were predicted not to result in any substantial reduction to the estimated detection rate. Nonetheless, allowance was made for non-detection of 10% of cysts that may be small i.e. 0.5cm^3. Similarly, the detection of kidneys showing signs of generalised carcase conditions as anaemia and uraemia were not considered to be adversely affected by kidneys not being palpated.

Conversely, the detection of Grade 1 nephritis (Appendix 1) in most cases is best detected by removal of the renal capsule. Grade 2 kidneys are easily detected by observation as they are characterised by a mottled whitish capsule, uneven surface and are often misshapen.

5.5.2 Estimating nephritis gross abnormalities as an indicator of potential zoonotic exposure with leptospirosis on a carcase basis

The specificity of Grade 2 abnormalities on an individual carcase basis is calculated from data reported by Chappel et al (1992) using Grade 1 and abnormality free kidneys combined as negative for leptospirosis.

5.5.3 Estimating kidney Grade 2 lesions as a herd surveillance tool for leptospirosis infected herds

As an alternative post-mortem inspection procedure may change the value of post-mortem inspection as a surveillance tool for zoonoses (CAC 2005), the effect on the proposed alternative is required for the equivalence assessment.

Herd sensitivity (SeH) and specificity (SpH) estimates for Grade 2 lesions as a test for leptospirosis infection in the herd were estimated using individual sensitivity and specificity estimates derived from data presented in Chappel et al (1992). This assumed both a 10% leptospirosis infection rate in positive herds, and plausible population and weekly slaughter lot sizes from 75, 250 and 1500 sow herds (Table 6).

Individual sensitivity/specificity estimates for enucleated Grade 2 kidney lesions were derived from data presented in Chappel et al (1992). Individual sensitivity/specificity estimates for unenucleated Grade 2 kidney lesions were subsequently inferred by assuming that Grade 2 lesion positive unenucleated kidneys form a subset of Grade 2 positive enucleated kidneys with a relative frequency of detection of 60%.

This estimate of relative frequency of detection is considered conservative in that unenucleated Grade 2 kidneys are easily detected by observation as they are characterised by a mottled whitish capsule, uneven surface and are often misshapen, and as a result may not be routinely enucleated anyway. By comparison, Willeberg et al (1997) found the relative frequency of detection of pericarditis in pigs of 80%, to be the same for palpation and observation.

Nonetheless, a very conservative approach was taken in estimating the effect of observing unenucleated kidneys on animal health and zoonotic surveillance. SeH and SpH were calculated for different numbers of Grade 2 lesion positive animals using the hypergeometric method (Cameron and Baldock 1998) and the Ausvet FreeCalc online calculator (Freecalc 2017). The optimum cut-point is the minimum number of Grade 2 lesion positive animals/sample which maximises both the sensitivity and specificity of the test for leptospirosis infection in the herd and was determined at the maximum of the product of SeH and SpH estimated over all possible cut-points.

Calculation of the cut-point, SeH and SpH for enucleated/palpated kidneys was based on sensitivity (29.5%) and specificity (95.7%) estimates for Grade 2 lesions in enucleated kidneys as a test for leptospirosis infection in an individual, using data reported in Chappel et al (1992).

Calculation of the cut-point, SeH and SpH for unenucleated/observed kidneys was based on imputed sensitivity (17.7%) and specificity (97.4%) estimates for Grade 2 lesions in unenucleated kidneys as a test for leptospirosis infection in an individual, estimated using data reported in Chappel et al (1992), and assuming that Grade 2 lesions in unenucleated kidneys form a subset of Grade 2 lesions in enucleated kidneys with a relative frequency of 60%.

6. Results

6.1 Hazard Identification

Foodborne outbreaks attributed to consumption of pig kidneys have not been reported in Australia for at least the last 25 years according to a search of the OzFoodNet outbreak database (Pointon et al., 2017).

Gross abnormalities of pig kidneys are listed in Table 2. Of these, only abscess poses foodborne risk (Pointon et al 2017). From a broader public health perspective, the enucleation of kidneys represents an occupational zoonotic risk as nephritis detected at slaughter in Australia is largely due to leptospirosis (Peet et al., 1983; Chappel et al., 1992).

The prevalence nationally of nephritis in pig kidneys has not been reported for a decade (Table 3), however, the most recent report (Pointon et al., 2008) may reflect a trend to fewer, smaller herds where control measures are less stringent.

Table 2 Foodborne significance of gross abnormalities of pig kidneys in Australia

Gross abnormality	Cause(s)	Foodborne Hazard (Yes/No)[1]
Abscess	*Rhodococcus equi*	No
	Trueperella pyogenes	No
	Staphylococcus aureus[2]	No
	Streptococcus spp.	No
	Burkholderia pseudomallei	No
	Salmonella spp. (?)	Yes
Septicaemia-petechial haemorrhages	*Salmonella* spp. (?)	Yes
	As for abscess	No
Lympho-reticular tumours	Neoplasia	No
Nephritis (including leptospirosis)	*Leptospira Pomona*	No
	As for abscess	No
Ureamia	Kidney infection	No
Anaemia	Bleeding disorders	No
Cysts	Developmental abnormality	No
Enlargement	Potentially current septicaemia including *Salmonella* spp.	Yes/No
Infarcts	Vascular occlusion – tumours, past septicaemis, vegetative endocarditis	No
Other unspecified		Uncertain

[1]Source APL Project 2015/023 Final Report 4 (Pointon et al., 2017: Appendix 2, Section 3)
[2]Pigs strains not attributed to foodborne illness (Pointon et al., 2017: Appendix 1, Section 1)
[3]Conditions leading to blood loss (Pointon et al., 2017: Appendix 1, Section 3)

Table 3 Lesion prevalence (%) in pigs at slaughter as recorded by state Pig Health Monitoring Scheme (Source: Pointon et al., 2008)

Lesion	SA		WA		VIC		QLD		NSW		Total**	
	1992	2006	1992	2006	1992	2006	1992	2006	1992	2006	1992	2006
Nephritis	7.3	2.1	2.8	1.6	NA	1.8	4.1	3.7	6.7	0.4	4.5	1.9

6.2 Prevalence of gross abnormalities and effect of observing unenucleated kidneys versus palpating enucleacted kidneys

The prevalence of gross abnormalities of kidneys is 6.43% of 84,047 pigs (95%C.I.: 6.27-6.60) (Table 4).

Only 0.014% of 84,047 pigs had gross abnormalities of food safety significance (1.4/10,000 carcases).

Of the 5,403 pigs with gross abnormalities, 65.0% had cysts.

Nephritis was detected in 2.0% of 84,047 pigs with 0.49% of 84,047 pigs having Grade 2 nephritis.

Generalised conditions (tumour, uraemia, anaemia) were detected in 0.04% of 84,047 pigs.

For pigs inspected by observation of unenucleated kidneys, the estimated increase in non-detection rates on a /10,000 carcase basis is estimated to be substantial for Grade 1 nephritis and moderate for grade 2 nephritis and cysts (Table 4).

Table 4 National snapshot of gross abnormalities of kidneys from 84047 pigs slaughtered over one week in seven export listed abattoirs and effect of observing unenucleated kidneys in an alternative post-mortem inspection procedure

Condition	Detected (n)	Detected (%)	Detection rate (per 10,000)	Non-detection rate (per 10,000) at an assumed 95% sensitivity[1]	Relative Sensitivity of unenucleated/observed compared with enucleated/palpated	Estimated additional non-detection rate (per 10,000) for unec/ob kidneys[2]
Abscesses	12	0.01%	1.43	0.08	80%	0.29
Nephritis (Grade 1)	1275	1.52%	151.70	7.98	10%	136.53
Nephritis (Grade 2)	413	0.49%	49.14	2.59	60%	19.66
Tumour	4	0.00%	0.48	0.03	90%	0.05
Uraemia	6	0.01%	0.71	0.04	99%	0.01
Anaemia	20	0.02%	2.38	0.13	99%	0.02
Cysts	3515	4.18%	418.22	22.01	90%	41.82
Others	226	0.27%	26.89	1.42	uncertain	

[1]Assumes a sensitivity of 95% for inspecting enucleated/palpated kidneys (AS4696:20017)

[2]This is in addition to existing non-detection rate of enucleation/palpation

6.3 Significance for carcase disposition judgement

A total of 27 of 84,047 inspected pigs with kidney gross abnormalities (0.032%) were totally condemned (95% C.I.: 0.021-0.047%) (Table 5).

Of these, five carcases were condemned for food safety reasons, four for septicaemia and one for pyaemia (i.e. 0.6/10,000 carcases).

Another five carcases were condemned for reasons unrelated to kidney lesions detected in that carcase i.e. pigs condemned due to arthritis (four) and pyrexia (one) that had cysts.

Kidney lesions alone may have been a major reason in one of the 27 total condemnations i.e. a tumour that may have signalled metastatic spread.

Table 5 Reasons for total carcase condemnation of 27 pigs with gross abnormalities of kidney; conditions in italics are of food safety significance

Condition	**Carcases condemned**
Anaemia	10
Arthritis	4
Emaciation	3
Malignant	1
Pyaemia	*1*
Pyrexia	1
Septicaemia[1]	*4*
Uraemia	1
Not specified	2
Total	**27**

[1]Includes one carcase condemned for septic pleurisy

6.4 Nephritis gross abnormalities as an indicator of potential zoonotic exposure with leptospirosis on a carcase basis

On an individual carcase basis at the point of post-mortem inspection, it is estimated that the specificity of nephritis Grade 2 gross abnormalities for infection with leptospirosis is 95.7% (Chappel et al., 1992)

6.5 Kidney Grade 2 lesions as a herd surveillance tool for leptospirosis infected herds

Results of herd sensitivity (SeH) and specificity (SpH) of Grade 2 nephritis for herd infection with leptospirosis when inspecting enucleated/palpated and unenucleated/observed kidneys are shown in Table 6.

For both current and alternative post-mortem inspection procedures a relatively low proportion of pigs in a slaughter lot with Grade 2 nephritis is indicative of a herd having a within herd infection rate of 10%.

Table 6 Herd sensitivity (SeH) and specificity (SpH) of Grade 2 nephritis for herd infection with leptospirosis when inspecting enucleated/palpated and unenucleated/observed kidneys

Herd characteristics				Enucleated kidney lesions[1]			Unenucleated kidney lesions[2]		
Sows	**Pigs/year**	**Farm N**	**Samples/wk**	**Cutpoint[3]**	**SeH**	**SpH**	**Cutpoint[3]**	**SeH**	**SpH**
75	1500	750	30	>=2	61.7%	62.8%	>=1	71.6%	45.4%
250	5000	2500	100	>=6	68.5%	73.9%	>=4	59.2%	73.7%
1500	30000	15000	600	>=33	91.7%	90.8%	>=20	85.7%	84.2%

[1]Based on sensitivity (29.5%) and specificity (95.7%) estimates for Grade 2 lesions in enucleated kidneys as a test for leptospirosis infection in an individual, using data reported in Chappel et al (1992).

[2]Based on imputed sensitivity (17.7%) and specificity (97.4%) estimates for Grade 2 lesions in unenucleated kidneys as a test for leptospirosis infection in an individual, estimated using data reported in Chappel et al (1992) and assuming that Grade 2 lesions in unenucleated kidneys form a subset of Grade 2 lesions in enucleated kidneys with a relative frequency of 60%.

[3]Cutpoint is the minimum number of Grade 2 lesion positive animals/sample which maximises both the sensitivity and specificity of the test for leptospirosis infection in the herd.

7. Discussion

When assessing the equivalence of alternative procedures for pig kidneys, it is important to include a thorough examination of zoonoses that occur in addition to quantifying the effect on food safety and wholesomeness. While leptospirosis has been included in previous slaughtercheck systems (Pointon et al., 1999), there is currently no systematic reporting back to producers of likely affected lots that have been detected at routine post-mortem inspection. Nonetheless, the value of current and alternative post-mortem inspection as a herd surveillance tool is provided for this equivalence determination.

7.1 Public health risk of gross abnormalities of kidneys

From a foodborne hazard perspective, the occurrence of gross abnormalities in kidneys nationally (Table 4) indicates these to be of negligible risk to consumers as indicated by the Hazard Identification step (Table 2).

However, from an occupational zoonosis perspective, there is evidence of a low rate of infection with leptospirosis. From an individual carcase inspection perspective, the incision of the renal capsule and handling to enucleate and subsequent palpation continues to pose a zoonotic risk. While Grade 2 nephritis, indicative of leptospirosis, might be currently condemned without enucleation and palpation, there is a likelihood of infected kidneys in these lots showing only minor Grade 1 gross abnormalities (Appendix 1) or are grossly normal (Chappel et al., 1992).

Alternative inspection procedures as observation of unenucleated kidneys would have a negligible effect on non-detection of gross abnormalities of food safety significance and would largely mitigate the zoonotic risk. In view of the zoonotic health risk posed by kidneys with nephritis, routine examination by means other than observation to inform disposition judgement requires use of personal protective equipment. When specifically retained for human consumption, observing enucleated kidneys represents a more precautionary approach that might be retained to limit zoonotic risk to those subsequently handling kidneys. This is based on the findings that three quarters of nephritis recorded were Grade 1 (Table 4), for which the non-detection rate is estimated to increase dramatically if kidneys are observed unenucleated.

Consequently, when kidneys are being retained for human consumption, lines of kidneys from lots of pigs in which Grade 2 nephritis is detected or suspected from previous lots from that source, should not be retained to avoid 'passing' infected kidneys that have minor or no gross abnormalities (Chappel et al., 1992). In consideration of the use of unenucleated kidneys for animal food, all identified hazards associated with gross abnormalities of pig kidneys (Table 2) would be inactivated by routine heat-treatment required for offal. Consequently, application of a disposition that allows unenucleated kidneys inspected by observation to be recovered for animal food (AS4696: 10.12(a)(iii)) is appropriate based on this evidence.

7.2 Evidence of wholesomeness

Wholesomeness is an issue for kidneys retained for human consumption. There is likely to be an increase in non-detection rates of Grade 1 and 2 nephritis and cysts arising from the observation of unenucleated kidneys, though the latter are probably mostly of minor in size. To achieve equivalence

for wholesomeness when intended for human consumption, observing enucleated kidneys is recommended.

7.3 Effect on determining carcase disposition judgement

All but one of the 27 pigs that were totally condemned with kidney lesions had major evidence for supporting total condemnation elsewhere in the carcase i.e. the kidney abnormality was unlikely to be critical for determining final carcase disposition. For many totally condemned carcases the presence of cysts was unrelated to the reason for total carcase condemnation. The one case of kidney tumour (Table 5) indicates metastatic spread necessitating total condemnation of the carcase and all its parts (AS4696:2007, Schedule 3). It is most probable that this abnormality would have been equally detected by observing unenucleated kidneys. On this evidence, observing unenucleated kidneys has a negligible effect on determining final carcase disposition

7.4 Effect on animal health surveillance

The value of detecting nephritis, especially Grade 2 abnormalities, as a herd surveillance tool has been promoted in slaughter surveillance programs (Pointon et al., 1999). Consequently, for the purpose of evaluating the effect of alternative post-mortem procedures (observation of unenucleated kidneys) on animal health surveillance, this effect has been estimated for a plausible range of herd sizes.

Based on estimated herd sensitivity (SeH) and specificity (SpH) estimates at optimum cut-off values, positive Grade 2 kidney lesions perform surprisingly well as a test for herd leptospirosis infection (Table 6). The performance of routine inspection is better in larger herds with larger weekly slaughter lot sizes. Consideration of both SeH (i.e. proportion missed) and SpH (likelihood of specific infection) are important in the interpretation of reports as a surveillance tool, especially when a low prevalence is reported.

Even assuming that examination of Grade 2 lesions in unenucleated kidneys may miss up to 40% of Grade 2 lesions evident in enucleated kidneys, observing Grade 2 lesions in un-enucleated kidneys still performs comparatively well as a test for herd leptospirosis infection (Table 6), but requires modification of the cut-off (i.e. minimum number of gross nephritis Grade 2 positive animals). This reduced estimate of relative frequency of detection is considered conservative in that unenucleated Grade 2 kidneys are easily detected by observation as they are characterised by a mottled whitish capsule, uneven surface and are often misshapen, and as a result may not be routinely enucleated anyway. By comparison, Willeberg et al (1997) found the sensitivity of detection of pericarditis in pigs of 80% to be the same for palpation and observation. Nonetheless, a precautionary approach was taken in estimating the effect of observing unenucleated kidneys on animal health and zoonotic surveillance by assuming up to 40% of Grade 2 kidneys might be undetected.

From these assessments (Table 6), a slaughter lot report with approximately 5% or more kidneys with Grade 2 nephritis reported is interpreted as being indicative of a within-herd leptospirosis infection rate of 10%. These data provide clinicians with an example of determining an action threshold for deciding when a more thorough diagnostic investigation might be undertaken to confirm the presence of active leptospirosis infection within a herd. This is consistent with the Code of Hygienic Practice

for Meat (CAC, 2005) which notes that the slaughterhouse is a key point in animal health surveillance, including zoonoses.

8. Implications & Recommendations

8.1 Routine Inspection

Issue

Key findings that underpin the equivalence of alternative post-mortem inspection procedures shown in Table 7 include:

- Procedures need to reflect product end-use i.e. kidneys retained for human consumption and those retained for animal food
- There is a negligible prevalence of gross abnormalities of food safety risk to consumers
- Observing unenucleated kidneys is estimated to have a negligible effect on non-detection rate for gross abnormalities of food safety significance, however, wholesomeness would be adversely affected for some gross abnormalities
- Kidney gross abnormalities have negligible value in determining the final carcase disposition judgement • Kidneys with Grade 2 nephritis are commonly infected with leptospirosis
- Observing unenucleated kidneys will reduce zoonotic risk to abattoir personnel
- Observing unenucleated kidneys remains a useful surveillance tool for identifying herds likely to be infected with leptospirosis.

Recommendation

Proposed alternative post-mortem inspection procedures for consideration by the AMRG are detailed in Table 7.

Table 7 Current and proposed alternative post-mortem inspection procedures for Schedule 2 AS4696:2007.

Current (AS4696: Schedule 2)	
Kidney (enucleated)	Observe
Alternative post-mortem inspection procedures	
Kidney (unenucleated)	Observe When not for human consumption
Kidney (enucleated)	Observe When for human consumption

Observing kidneys is consistent with previous AMRG approval for routine visual inspection of pigs based on the final report of APL Project 2015/023. This also provides for palpation if considered suspect or if needed to inform carcase disposition judgement. A consequential consideration arising from potential approval of this alternative procedure relates to use of kidneys for pet meat (Anon 2006). In this regard, infectious agents potentially associated with kidney abnormalities detected in this assessment (Tables 2 and 4) would be inactivated by heat treatment used for pet meat (AS2006).

8.2 Location of inspection

Issue

As kidneys have negligible value for determining final carcase disposition, the option for enucleating and inspecting (by observation as in 8.1 above) in the offal room arises for those retained for human consumption.

Recommendation

That kidneys retained for human consumption may be inspected by observation of enucleated kidneys at sites other than the slaughter-floor e.g. offal room.

8.3 Animal Food

Issue

In consideration of the use of unenucleated kidneys for animal food (AS4696), all hazards associated with gross abnormalities of pig kidneys identified would be inactivated by routine heat-treatment when used for animal food.

Recommendation

That the disposition applied to unenucleated kidneys inspected by observation allow these to be recovered for animal food under AS4696: 10.12 (a) (iii).

8.4 Effect of observing unenucleated kidneys on animal health (zoonosis) surveillance

Issue

As observing un-enucleated kidneys Grade 2 kidney lesions performs surprisingly well as a test for herd leptospirosis infection, these alternative post-mortem inspection procedures remain a useful herd surveillance tool for leptospirosis.

Recommendation

Nephritis (Grade 2 especially) should be included in the producer feedback project to foster greater control of leptospirosis to mitigate zoonotic risk of farm, transport and abattoir personnel.

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8.5 Submission for determination of equivalence by the AMRG

Issue

This report has been drafted to address the requirements of proposals for consideration of equivalence with the Standard (AS4696).

Recommendation

That this report be submitted by APL to the AMRG for consideration in time to be included in Version 1 of Schedules 2 and 3 in early 2018.

9. Intellectual Property

None.

10. Technical Summary

Start text here. Summary of information developed as a part of the research, eg. discoveries in methodology, equipment design etc.

11. Literature cited

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12. Publications Arising

Nil.