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IMPLEMENTATION OF FOOD SAFETY PROGRAMS

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SUMMARY
Domestic and international consumer food safety concerns are increasingly reflected in international trade agreements and domestic food safety legislation. The process of risk assessment provides the framework for relating food safety measures to public health outcomes, and thereby a scientifically objective basis for selecting and implementing food safety procedures at the appropriated points along the food supply-chain. A survey of food industry stakeholders in Australia strongly endorsed greater utilisation of risk assessment on a through-chain basis for the development of biologically valid food safety measures and their willingness to collaborate. This approach equally applies to the primary sector and has ramifications for the epidemiological and diagnostic rigour of research studies designed to underpin the development of food safety risk management options for industry. Stakeholders also identified the need to enhance food borne hazard surveillance in the primary sector and integrate this with public health surveillance.

Keywords: Food safety, risk assessment, surveillance, review

INTRODUCTION
Domestic and international consumers can ingest our foods and beverages with confidence they will not become ill. However, policy makers and technical experts throughout the food sector agree there is a much richer texture to the issue of food safety than the simplicity of whether it is “safe” or “unsafe”.

Currently, food safety is viewed as being a matter of assessing and managing the hazards we know of, within the limits of currently available technology and at acceptable cost. The real questions in food safety can more accurately be characterised as relating to the degree of safety, the circumstances and at what cost this is being met. In addition our food industries, policy makers and regulators confront numerous emerging issues which pose new challenges. These issues have the potential to threaten public health and the current confidence in our food industries. These challenges include new and emerging microbial hazards, eating/lifestyle changes, new foods and combination and replacement meals and new production and business models for providing foods. It is also recognised the food industry, with its farming, manufacturing and distribution base, is a major contributor to the national economy. As such, it is in the national interest to strive continuously to ensure food safety standards are achieved cost-effectively and our "clean and green" claims can always be substantiated.

The scope of this paper will cover the perspective of a broad range of food supply-chain stakeholders on food safety issues extracted from a recent report researched by the author (Anon, 2002a) and the implications of these for the primary sector.

FOOD SAFETY ENVIRONMENT
International context
The Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues (FAO/WHO, 1995) provided FAO, WHO, CODEX Alimentarius Commission (CAC) and member countries with advice on practical approaches for the application of risk analysis to food standards issues. An underlying tenet is that barriers to trade must be based on scientific evaluation of risk to human health. Since then, the CAC has progressed in developing international food standards based on risk assessment and risk analysis principles. The FAO/WHO Expert Consultation on Microbiological Hazards in Foods (FAO/WHO, 2000) recommended:

“FAO and WHO countries promote the systematic investigation of outbreaks of food borne illness and collect information useful in microbiological risk assessment. In particular, epidemiological and microbiological information (eg. the number of pathogens per gram of food implicated in outbreaks) will improve the basis for dose-response assessments.”

The "Principles and Guidelines for the Conduct of Microbiological Risk Assessment" (CAC, 1999) provided an impetus for an international approach. This framework has led to the joint FAO/WHO activities on risk assessment (FAO/WHO, 2000) of microbiological hazards in foods including *Listeria monocytogenes* in ready-to-eat foods and *Salmonella* spp. in broilers. In addition, the FDA/USDA in the United States developed a "Draft Assessment of the Relative Risk to Public Health from Food borne *Listeria monocytogenes* Among Selected Categories of Ready-to-eat Foods" (FDA/USDA, 2001). The assessments provide an international benchmark in methodologies to improve food safety. The assessments also provide a mechanism by which the food safety equivalence of alternative production systems can be evaluated.

The Commission of the European Communities White Paper on Food Safety (COMMISSION, 1999) is a further step toward adopting risk assessment processes to underpin food safety. However, while risk assessment should be "used as a shield rather than a sword", the genuine concern in the electorate also provides a convenient additional instrument for protectionism, which is rampant in international trade in agricultural commodities.

At a meeting of the recently reactivated CODEX Committee on Meat and Poultry Hygiene (Anon, 2002b) important principles related to the primary sector were adopted: "Meat hygiene requirements should involve the entire food chain continuum in the control of hazards. As appropriate to the circumstances the results of routine monitoring and surveillance of animal and human populations for food safety purposes should be considered in the review and/or modification of meat hygiene requirements." These international standards establish a framework for the development of appropriate quality systems for the entire food-chain which underpin export trade access. The primary sector can, therefore, expect to see increasing pressure from processors, exporters and regulators to implement effective food safety measures.

Australian food safety policy and regulatory developments

In 1996 Australian Governments, in partnership with the food industry, set out a blueprint for an enhanced, coordinated food system encompassing the whole of the food supply-chain from primary producer through to end consumer. The National Safe Food System Model aimed to increase consumer confidence, enhance Australia's performance as a world benchmark for safe food production and make more effective utilisation of Government and industry.

It incorporates the following key components National Food Hygiene Standard, implementing HACCP systems, monitoring and surveillance, emergency arrangements, training and education. In relation to research it proposed; "Priority must be given to developing the body of scientific information available to industry for risk assessment and management. Structures and processes for ensuring Government, research and development organisations and industry exchange current industry-based risk assessment data should be instituted" (National Safe Food System Working Group, 1997).

A review of Food Safety Regulations (Blair, 1998) aimed at reducing the regulatory burden on the food sector, examining those regulations which restrict competition, impose cost or confer benefits on industry, and improve the clarity, certainty and efficiency of food regulatory arrangements. In relation to research it proposed government and industry surveillance of food borne illness, zoonotic and animal diseases combined with data from food product surveillance for microbiological, chemical and other contaminants can be used to generate a comprehensive food safety database. The report stated that: "Research is important to our understanding of food borne illnesses and to develop and assess the effectiveness of food safety programs and policy. To assess the safety of various food commodities we need to know more about the hazards in these products and their relation to adverse health outcomes. Research into food borne pathogens and food contaminants must be broad to address information needs at all points along the paddock-to-plate continuum. Research should particularly focus on current gaps in knowledge. The research agenda should also be guided by the international recognition that food safety policy be based on risk assessment. Risk-based assessment inclusive of strong scientific evidence through surveillance and research from paddock to plate, can provide valuable information about Australia's food safety system". It also ensures that countries, including Australia, establish scientifically sound food safety policies and provide a mechanism for making informed comparisons of food safety between trading partners.

While Blair (1998) went on to observe that the elements which comprise a national safe food system are currently in place, "they are not integrated". In response to the Blair Report, the COAG, Senior Officials Working Group on Food Safety (Anon, 2000) developed a Model Food Act that provides a flexible, outcomes based approach necessary for cost efficiencies, a streamlined, nationally focussed system that involves all stakeholders; and a process that takes as its base proposition all food business operators have a civil responsibility to supply safe food. The model was adopted through the signing of the Inter-Governmental Agreement (IGA) in 2000. The streamlined bi-national system of food regulation includes a single Australia and New Zealand Food Regulation Ministerial Council to develop domestic food regulation policy and policy guidelines for the development of domestic food standards, a Food Regulation Standing Committee to support the Ministerial Council, a single set of domestic food standards consistent with CODEX, a single, independent, expertise-based, statutory agency called Food Standards Australia New Zealand which develops all domestic food standards and a single Food Regulation Consultative Council made up of high-level representatives of stakeholder peak bodies to provide advice to the above bodies.

Since that report there has been considerable progress in harmonising food safety legislation nationally, developing and implementing food standards nationally, implementing industry-driven programs and developing individual quality assurance schemes by the larger food enterprises. Subsequently, food safety standards developed by ANZFA in conjunction with state and territory health authorities, were the subject of an Inter-Governmental Agreement (IGA) in late 2000. These are evidence-based and consider standards developed by the CODEX Alimentarius Commission and countries including the United States, Canada and the United Kingdom. The standards were drafted to provide industry with more flexibility to achieve safe food outcomes by incorporating modern food safety practices and removing outdated and prescriptive requirements. ANZFA also conducted a review of the microbiological standards in the joint Food Standards Code (ANZFA, 2001). Risk analysis was conducted for 26 food groups and for each group microbiological hazards of concern, (ie pathogenic microorganisms) were identified and ranked according to their relative risk to the consumer. Guideline levels for these hazards in specific commodities are being recommended. While they are not legally enforceable they do provide a framework for industry to maintain the lowest achievable levels for microbiological hazards in food.

Public health record: risk ranking

The profile of microbial hazard:product pairings for meat and meat products over the past decade is shown in Table 1. The rare involvement of fresh meat in outbreaks of food borne disease supports the observation of Sumner *et al* (2000) that temperature abuse has been a constant problem spanning several decades of food borne illness. While food processing, storage and handling are attributed the ultimate blame for outbreaks, both the large food processors and primary industry regulators placed great emphasis on better control of hazards in the primary sector from where many major hazards arise (Anon, 2002a). Furthermore there was agreement that risk assessment provides the framework and justification to shift the emphasis of industry and regulatory programs from fresh to processed meats and to other commodities such as sprouts which have been the cause of major food borne outbreaks internationally.

The focus on control of hazards in the primary sector is further reinforced in the CODEX Proposed Code of Practice for Fresh Meat (Anon, 2002b) which states that "Primary production is a significant source of hazards associated with fresh meat. A number of microbiological hazards are present in animal populations intended for slaughter and their control at farm level often presents considerable challenges eg. *E coli* O157:H7, *Salmonella* spp. and *Campylobacter* spp. A risk management approach to meat hygiene includes consideration of risk management options that may have a significant impact on risk reduction when applied at the primary level of production." The proposed Code also strongly advocates "meat hygiene requirements should involve the farm-to-plate continuum so as to optimise the control of hazards throughout the food chain."

The Australian meat industries have been progressive in this regard. Risk-based food safety strategic research and development plans have been implemented by the red meat (Fabiansson *et al*, 1996) and pork industries (Pointon, 1997) and have benchmarked food borne hazard levels to underpin export market access (Phillips *et al*, 2001; Coates *et al*, 1997). The Microbial Food Safety Key Program of

Meat and Livestock Australia focussed on: the ecology and prevalence of meat borne pathogens; new systems and technologies to minimise the risk from those pathogens; and communication and education of industry and food service workers, and consumer, as an important part of the risk minimisation strategy (Ross, 1999).

Another important determinant of risk characterisation (estimation) is the susceptibility of the population. The percentage of the Australian population predisposed to food borne disease for one reason or another (Table 2) is estimated to be 20.5% (Anon, 2001). This is consistent with estimates from other Western industrialised countries (20%-25%) and is projected to increase due to increased proportion of > 60 year olds over the next 20 years.

Table 1. Reported Australian outbreaks associated with meat and meat products for the period 1990-2000 (Source: Anon 2001)

Year	State	Product	Pathogen	Cases	Deaths
1990	WA	Pate, Pastrami (?)	*L. monocytogenes*	11	6 (stillbirths)
1991	SA	Salami	*S.* Anatum	>120	
1992	WA	Salami	*S.* Typhimurium	>120	
1994	SA	Pork sausage	*S.* Enteritidis	14	
1995	SA	Salami	*E. coli* 0111	150-22 (HUS)	1
1996	QLD	Not identified, a single delicatessen implicated	*E. coli* 0157	6	
1996	VIC	Cold roast meat	*C. perfringens*	33	
1996	SA	Diced chicken	*L. monocytogenes*	5	1
1996	SA	Bread rolls with meat filling	*S.* Typhimurium PT 135	71	
1997	VIC	Corned silverside	*S.* Muenchen	24	2
1997	VIC	Meat rolls	*S.* Typhimurium 1	>700	
1997	VIC	Unknown	*S.* Typhimurium 43	7	1 (?)
1997	VIC	Corned silverside, leg ham and Virginia ham	*S.* Anatum	25	
1997	VIC	Unknown	*S.* Chester	25	
1998	SA	Spatchcock (game bird)	*S.* Typhimurium RDNC A045	38	
2000	SA	Chinese food from another single restaurant	*S.* Typhimurium RDNC	6	
2000	SA	Asian food from a single restaurant	*S.* Typhimurium phage type 44	11	

Table 2. Factors that predispose people to food borne infections and the proportion of the Australian population in those categories (Source: Anon 2001)

Susceptibility Factor	Percentage of Australian Population in this Category
Age > 60 years	13.70%
Age ≤ 5 years	4.6%
Cancer	0.39%
Transplants	0.08%
AIDS	0.11%
Diabetes	1.88% (and believed to be rising)
Pregnant	1.13% (29500 births per annum. Pregnancy last 9 months. Multiple births ignored)
Kidney disease	0.07%
TOTAL PERCENT SUSCEPTIBLE	20.5%

Risk assessment and HACCP

Developments in the global trade of food have exposed primary producers to a new set of opportunities and risks that are best managed with risk assessment. Estimating 'equivalence' is now the process used to determine whether or not Australian products can penetrate foreign markets, and whether or not products produced abroad can penetrate Australian markets. This involves an appraisal of whether the imported product presents the same or lesser magnitude of human-health risk as posed by the domestic product. Under the guidelines produced by the World Trade Organisation (WTO), the assessment of equivalence demands the conduct of a food safety risk assessment by the importing country. A country can deny the entry of a product if it fails to meet the equivalence standard. Thus nations wishing to trade in primary products in particular require a pool of scientific expertise to conduct their own risk assessments on the products and also to appraise the appropriateness of those produced by their trading partners. At the domestic level, state food safety legislation and food standards are also likely to be based on the risk assessment approach. It is timely, therefore, for industry to develop an integrated through-chain approach to food safety that has international standing.

Quantitative risk assessment is a methodology used to organise and analyse scientific information to estimate the probability and severity of an adverse event such as food poisoning (Cassin *et al*, 1998). It combines the scientific disciplines of epidemiology, predictive microbiology, statistics and through-chain process modelling. While models may estimate consumer risk they are not being used to set microbiological standards (Food Safety Objectives – Anon, 2002b). Discussions in relation to the development and potential utilisation of Food Safety Objectives (FSOs) is in the scope of the CODEX Committee on Food Hygiene. The position of the Australian delegation (Bailey, pers com) to the CODEX Committee on Hygienic Practices for Fresh Meat on FSOs was that these would be difficult to set for fresh meat considering the potential for product abuse post-retail (Jay *et al*, 1999).

However, through-chain process risk models provide the capacity to evaluate risk mitigation strategies (importance analysis). In a risk model for *E. coli* O157:H7 in ground beef hamburgers an 80% reduction in the likeliness of illness is attributed to appropriate temperature control of fresh meat, whereas a 46% reduction was predicted by effective preslaughter reduction and 16% attributed to limited compliance to increase cooking temperatures (Cassin *et al*, 1998).

In this manner risk assessment has the capacity to differentiate between hazards in terms of consumer risk and identify and rank risk management options. While the Hazard Analysis Critical Control Point (HACCP) system entails a hazard analysis step it does not provide a method to quantify hazards and their consequences, or how to set critical limits in relation to the acceptable level of protection. HACCP provides the best mechanism by which the microbiological safety of food can be assured through the control of hazards at their source, product design and process control, and the application of good hygienic practice through-chain to the consumer (FAO/WHO, 1995). Risk assessment thereby provides essential information for the implementation of effective food safety HACCP programs. In recognition of this Meat and Livestock Australia has funded a national training program for risk managers (Anon, 2001).

METHODOLOGY: FOOD SUPPLY-CHAIN STAKEHOLDER VIEWS

This review provides excerpts from a broad range of stakeholders and agencies with regulatory responsibility covering the breadth of the food supply-chain (Anon, 2002a). This entailed interviewing and surveying the following sectors; large food processors, primary industry, small to medium enterprises, primary industry and food processor regulators, large food retailers, federal regulatory agencies, FAO/WHO expert consultants, food borne hazard surveillance programs and the insurance industry. The focus of the study was on issues beyond the capability of a company, agency and supply-chain sector. Research needs, expectations and priorities of these stakeholders were identified. A gap analysis to identify unresolved needs was conducted against a background of research capability and direction. As part of the research needs survey, the primary production and large food processing sectors were surveyed in regard to having quantitative levels of contamination on produce and retail-ready products. Their willingness to make this data available in a risk assessment process to define appropriate and achievable food safety standards and measures was also assessed.

Food supply-chain stakeholders' perspective

Large Food Processors. The Technical and Quality Managers of most (11) of the major food processing companies were interviewed (Table 3). The food safety issue most frequently raised was the identification and control of hazards on-farm. This predominantly related to microbial hazards. This was supported by a majority of respondents who ranked as a high priority emerging food borne (zoonotic) agents, (eg, BSE, *E. coli* 0157:H7, etc), which have emerged in the primary sector as a major threat. The view "we can control what we know about", underscores a moderate ranking for current common food borne agents provided by this sector.

Recognising risks posed, in part, by the primary sector is reflected in the high importance placed on the need for through-chain risk assessments. While microbiological hazards are considered the major risk, some respondents highlighted the need to keep residues, especially pesticides, and allergens in check. These would be included in the Hazard Identification and Hazard Characterisation steps of a Risk Assessment.

Table 3. Ranking of food safety issues by large food processors (Anon. 2002a)

ISSUE											
	1	2	3	4	5	6	7	8	9	10	11
Emerging Food borne Agents											
Effect on Food Safety	H	M	M	H	H	H	M	H	H	M	M
Effect on Business	H	M	L	H	H	H	H	H	H	M	M
Human Health Implications of Zoonoses											
Effect on Food Safety	M	L	M	H	H	H	M	M	H	L	M
Effect on Business	H	H	M	H	H	H	H	M	H	L	M
Current Common Food borne Agents											
Effect on Food Safety	M	M	H	H	M-H	L-M	H	M	H	L	M
Effect on Business	M	M	H	H	M-H	L-M	M-H	L-M	H	L	H
Through-Chain Risk Assessment											
Effect on Food Safety	M-H	M	H	H	H	H	H	H	H	M	H
Effect on Business	M-H	M	L	H	H	H	H	H	H	M	M
Minimally Processed Foods											
Effect on Food Safety	H	H	L	H	L	M	H	H	H	L-M	M
Effect on Business	H	L	L	H	L	H	H	M	H	L-M	M
Antibiotic Resistance Carried by Food borne Agents											
Effect on Food Safety	L	L	M	M	H	M-H	H	L-M	M	L	H
Effect on Business	L	L	M	M	H	H	M	L-M	L	L	M
Value of Non-Human Micro Databases as "Early Warning"											
Effect on Food Safety	M	M	M	M	H	M	L	L	H	M	L
Effect on Business	M	M	L	M	H	M	L	L	L	M	H
Practical Food Safety Plans for Small Business											
Effect on Food Safety	M	M	L	H	H	H	H	H	H	L	M
Effect on Business	M	H	L	H	L	H	H	H	H	L	H
Improved Implementation of Food Safety Practices in the Home											
Effect on Food Safety	M-H	M-H	H	H	M	L	H	H	H	L	L
Effect on Business	M-H	M-H	L	H	M	L	H	H	H	L	M
Quantitative Data (Y/N)	Y	-		Y	Y	Y	Y	Y	Y	-	-
Data Sharing (Y/N)	Y	-		Y	Y	Y	Y	Y	Y	-	-

Of importance was establishing levels of contamination of produce and foods in Australia against which assessment of imported products can be judged ("equivalence"). This was a reflection of the high regard held for risk assessment procedures.

Many respondents raised the issue of the changing risks associated with the move to minimally processed foods, including the knowledge of the risk posed by *Listeria monocytogenes* in Australia and the requirements for the whole-of-industry. Another component is the behaviour of a range of microbial hazards in multi-component meal replacements. As ingredients from a range of supply-chains are combined, dependence increases on the food processor of the control of hazards by suppliers, ie. primary producers.

The implementation of HACCP procedures in this sector in large part is established. However, concern was raised in regard to its validation. There is a need for rapid test procedures for common food borne agents that give quantitative results. Concern was also raised of poor food safety QA in the SME sector, particularly at the food handling/retail level. When specifically asked to rank the importance of QA in the SME sector, the response was generally "high". There was a strong impact on the business of large processors resulting from product failures due to SME problems, although strong brand names are more resilient.

Also of concern was traceability, foreign matter (eg glass during processing), regulatory enforcement of on-farm QA, over-regulation and the need for technology development in the area of "processing lethality".

In relation to research needs the use of risk assessment was recommended to better identify and quantify hazards on-farm, relate levels of contamination in foods to consumer risk (better human surveillance – OzFoodNet role), set standards (Food Safety Objectives) using quantitative measures, identify data gaps (and research priorities) using quantitative measures and investigate new hazards and those with potential to emerge in minimally processed foods (eg *Listeria monocytogenes*).

In considering improved hazard identification, the issue of improved surveillance utilising non-human microbiological database (incorporated in the National Enteric Pathogen Surveillance Scheme, Hogg, 2001) was raised. The question of the value of non-human database serving as an "early warning" system was equivocal. The value in (retrospective) investigations was recognised, however, respondents felt this data "won't keep you out of prison." Despite the "low" ranking it was noted by one respondent that this should be undertaken as a whole-of-Government approach with integration of public health and primary industry programs.

Other research needs identified were developing rapid quantitative tests for priority hazards, extending shelf-life without increasing risk, self-evident additives/bio-markers to indicate failures, improving "kill steps" in processing and using molecular technologies to identify virulent strains.

In relation to what stakeholders would like to see happen to address these issues, the following comments were made. There is a strong feeling that applying risk assessment across the whole supply-chain be given high priority by Government. This process would provide data on levels of contamination of Australian products as a basis of establishing systems that support continuous quality improvement, supporting improved consumer protection and export market access. This would require an industry and Government approach to funding and establishing priorities for research to address quality assurance issues. Industry needs a forum to explore these research opportunities and directions.

There is a need for a greater focus on developing pro-active risk-based surveillance programs where responsibilities are defined, "otherwise no-one does anything". Included in this is a need to "focus resources on prevention, rather than after the event investigation." Guidelines need to be improved, based on Australian data, rather than greater regulation. Allied to this was the questioning of the mandatory notification of *Listeria monocytogenes* and its inconsistent application across states. It was noted "regulation won't achieve anything alone". While risk assessment may indicate application of regulatory measures (ie level of contamination/food safety objective), the process also provides a broader perspective of the benefit of other food safety measures (non-regulatory), which may improve risk reduction.

In relation to sharing data for risk assessment purposes the large processing sector keeps quantitative data on products, which it was prepared to make available. This came unofficially as final authorisation would be "up to management". However, in a targeted, de-identified and carefully managed process which does not penalise companies, it was felt that the data would be made available. The quality of this data would need to be evaluated, particularly in relation to test methods and sampling frameworks. To ensure future data collected meets international risk assessment standards, discussions should be held to establish the practicality, and cost-effectiveness of building epidemiological, sampling and testing specifications into routine company testing programs.

Small and medium enterprise sector issues. The perspectives of the SME sector's issues and potential research needs were obtained from technologists serving thousands of SME businesses (Table 4). These perspectives were strongly and consistently reinforced by the large food processor and large retail sectors (Anon, 2002a).

While a number of business risks and barriers to implementing food safety plans were cited, there was a strong feeling that poor risk perceptions among SME business managers and staff are the underlying problem. There is an extremely poor understanding of hazards and how processes in SME business can increase consumer risk. This will be a major barrier to increasing the relevance and importance attributed to food safety by the SME sector.

This observed low-risk perception is seen as the main reason for the "low" ranking by the SME sector for a range of food safety issues which were ranked "medium to high" by other stakeholders (Table 3). This is the glaring divergence of opinion between the five stakeholder groups which ranked these issues and therefore, presents a major barrier to the adoption of through-chain approaches to food safety. Lack of assurance of product integrity by one sector, however, must not delay the drive to implement effective food safety risk management programs by other sectors.

Surveillance systems. A recent review of Australia's animal disease surveillance systems, "Animal Disease Surveillance Program: Baseline Study" (Ausvet, 2001), commissioned by Animal Health Australia and the National Veterinary Committee has been conducted.

One of the major conclusions is there is no process for risk-based prioritisation of investment in surveillance programs. As a large proportion of food borne pathogens exist asymptomatically in animal populations, and production and marketing practices may increase levels, it is important food safety be included in the "risk-based" prioritisation process. Resources to facilitate this shift in emphasis are not apparent. A recent risk analysis workshop convened by Animal Health Australia, however, ranked this issue of "high" importance in terms of a threat to the Australian livestock industries. This issue was one of the top five issues ranked "high" to be referred to the Animal Health Australia Board for consideration. Inputs to the workshop were sought from this food safety research needs study.

Animal Health Australia, which brokers the co-funding of animal health programs on behalf of industry and Government, recognises the increasing importance of food safety in its "Animal Health 2010: A Report of the Strategic Destinations Group" (AHA, 2000). Conclusions drawn include:

- industry funded programs developed and managed by AHA are overwhelmingly aimed at securing export trade access;
- while some research is funded within some programs, industry investment is attracted on the basis of implementing actual disease control programs;
- programs do not cover control of infection/contamination of herds and flocks with food borne pathogens which are asymptomatic in animals; and
- data on the level of contamination of flocks and herds with food borne pathogens is held mostly by industry research and development agencies, though some states (NSW) are starting benchmarking surveys on primary commodities.

Table 4. Ranking of food safety issues for small and medium enterprise food processors and retailers (Anon. 2002a)

ISSUE	QA Consulting and Auditors						Industry Association		Education	
	1	2	3	4	5	6	7	8	9	10
Emerging Food-borne Agents			meat							
Effect on Food Safety	L	L	L	L	H		N/A	L	L	
Effect on Business	L	L	L	L	M		N/A	L	L	
Human Health Implications of Zoonoses										
Effect on Food Safety	L	M	L	L	-		N/A	M	L	
Effect on Business	L	L	L	L	-		N/A	M	L	
Current Common Food-borne Agents										
Effect on Food Safety	L	H	L	M	H		N/A	M	M	
Effect on Business	L	M	L	H	M		N/A	M	M	
Through-Chain Risk Assessment										
Effect on Food Safety	L	L	M	M	M		N/A	L	M	
Effect on Business	L	L	M	M	M		N/A	M	M	
Minimally Processed Foods										
Effect on Food Safety	L	H	L	L-M	M		N/A	L	L	
Effect on Business	L	L-M	L	L-M	L		N/A	L	L	
Antibiotic Resistance Carried by Food-borne Agents										
Effect on Food Safety	L	L-M	L	L	L		N/A	L-M	L	
Effect on Business	L	L	L	L	L		N/A	L-M	L	
Value of Non-Human Micro Databases as "Early Warning"										
Effect on Food Safety	L	L	L	L	L		N/A	M	-	
Effect on Business	L	L	L	L	L		N/A	-	-	
Practical Food Safety Plans for Small Business										
Effect on Food Safety	M-H	M	M	H	L		N/A	H+	-	
Effect on Business	-	H	M	M	M		N/A	H+	-	
Improved Implementation of Food Safety Practices in the Home										
Effect on Food Safety	L-M	H	L-M	M	M		H	H	L	
Effect on Business	L	H	-	M	L		H	H	L	
Quantitative Data (Y/N)	-	-	-	-	-		H	-	-	
Data Sharing (Y/N)	-	-	-	-	-		N/A	-	-	

The greater emphasis given to surveillance for food safety pathogens is apparent in the recent "South Australian Animal Health Service, Strategic and Business Plan 1999 – 2002". This is an example of how agencies are responding to the issues identified in previous reviews (PIRSA, 2000). Specialist veterinary epidemiologists are being recruited to develop programs that more directly target food safety risk.

The Australian Veterinary Association is also developing a policy on the *Food Safety Role of Veterinarians.* The policy under development (Kevin Doyle, pers comm) will address where practicing veterinarians fit in with the broader paradigm of food safety.

In Australia, the National Enteric Pathogen Surveillance Scheme (Hogg, 2001), addresses all human and non-human isolates including veterinary, human foods, industrial and other environmental isolates. It relies on important links forged with laboratories providing the information, the trust of industry and usefulness to those with a need to develop action plans within their jurisdictions. This provides a (mostly) passive surveillance role, however, it provides an essential resource to collaborate with and support any wider active surveillance role which has been repeatedly advocated in the reviews cited.

The National Residue Survey provides a comprehensive surveillance program for metals, chemical and antibiotic residues across the major livestock commodities (O'Flynn, 1999; NRS, 2001). The monitoring of meat products is designed to ensure compliance with the Australian Standards for Hygienic Production of Meat for Human Consumption to meet export certification requirements of AQIS and trading partners. The sampling frameworks have been reviewed and accepted by the USDA and EU as "scientifically sound, based on valid risk assessment and structured to deliver statistically valid results". Samples are tested for a broad range of organochlorine, organophosphate and PCB chemicals and metals. Violation rates are extremely low, and due exclusively to chemical residues in cattle and predominantly metals for sheep (NRS, 2001).

IMPLICATIONS FOR THE PRIMARY SECTOR

Through-chain risk assessment perspective

The endorsement to adopt risk assessment as a driver to improvements in food safety is almost universal among food industry stakeholders. For some time Australian regulatory authorities have been promoting this framework and the Model Food Bill incorporates the flexibility of outcome based standards and the principle of equivalence. This reflects the international approach being taken by FAO/WHO and the CODEX Alimentarius Commission.

The Australian consultants to FAO/WHO expert consultations on microbiological hazards who were interviewed, consistently emphasised that the international risk assessments conducted by FAO will increase the imperative to move from qualitative to quantitative assessments which utilise Australian data. This capability will better position Australia to contribute to "the interpretation of equivalence, at the international table."

Inherent in the consistent feedback is the need to conduct risk assessments across the supply-chain. While risk assessments on product/hazard pairs and at the sector level are the focus of most risk assessments, the move to through-chain assessments as part of a process to produce quantitative consumer risk estimates is endorsed. This process will, in turn, identify data gaps which require targeted research. This process will enable the implementation of food safety measures (including regulations where appropriate) which are related to public health outcomes and are based on the performance of industry and what industry should achieve to ensure an acceptably safe food supply.

Some stakeholders are critical that Australian risk assessments are not of international standing and lack quantitative data on the level of food borne contaminants. This is considered essential by large food processors, primary industry and regulators to establish appropriate food safety measures for the Australian food industry. The consultants also noted a need to conduct quantitative risk assessment, "to be an international player" to assist in maintaining of our reputation for "clean and green" food. At present no-one in the world is using this approach to set microbiological hazards, however, the approaches and methodologies are being developed and Australia needs to stay competitive. "Importance analyses" within risk assessments (Cassin *et al,* 1998) are being utilised to identify the

points along the supply-chain which contribute substantially to risk, and therefore, should be the focus of practical and effective control measures.

Risk managers (industry and regulators) need to clearly identify the priorities for risk assessment research. This recommendation is proposed as while considerable research in food safety is conducted, much of the work is not structured to address gaps in knowledge required by the risk assessment process. This not only requires risk managers (regulators and industry) to define the research questions but also requires the research to meet epidemiological and laboratory standards essential for risk assessment and the international recognition of outputs. These are fundamental tenets on which future food safety research which supports the food safety management should be based.

All stakeholders in the supply-chain should promote adopting the risk assessment framework to research investors to provide the basis for commissioning food safety research in their jurisdiction. Peak industry bodies with risk management responsibilities should define the research questions for risk assessment research accordingly.

Type of data and gaps

Many stakeholders criticised the lack of Australian data in risk assessments. When the proposition was put to industry to make industry data available for high priority risk assessments, there was strong agreement from both the large food processor and primary industry sectors. The value in the data collected by these agencies and companies lies in providing quantitative levels of contamination on ingredients and finished products. This is critical information for risk modellers in the prediction of consumer exposure and to conduct "importance analysis" through-chain to identify control points.

There are several advantages to this approach:

i) This data would (in confidence) benchmark the performance of Australian industry and enable an assessment of the current levels of contamination to consumer risk. Food safety options stemming from this process would then take into account the industry (sector) contribution to risk and whether improvements are required and achievable. This will also identify additional information needs and can be used to influence research investment priorities.

ii) Without this data the actual contribution of industry sectors to risk will be a broad estimate at least, drawing on-going industry and regulator criticism.

iii) By contributing this data, industry will be provided with a food safety perspective of its overall contribution to risk and where and how much resource should be directed toward this issue. Trade and legal requirements will also determine this commitment.

iv) To make this information available, the industry/company sector will need to be involved in the risk management process. This will include defining research questions and is particularly important in the selection of risk management options as there is heavy reliance on industry to implement appropriate food safety measures.

Under the present arrangements for industry to submit data for risk assessment processes, there are several difficulties and issues to be addressed. These include the sampling frame used so data is representative of product volume flows and seasonality of hazards (where appropriate), consistency of laboratory methodology and the need to meet a required international standard, the fear of being penalised if test results are "out of specification" and de-identification and security to ensure commercial confidentiality.

These are important and difficult issues which will require fail-safe systems to overcome. However, this "approach must be nurtured" to harness the potential savings and the relevance of outputs and partnership approach achieved. Existing arrangements, that protect contributed data from the Freedom of Information Act and subpoenaing, should be investigated.

While attempts to access quality data from industry have been made in the past, efforts should be continued as industry showed a clear and strong commitment to the process. While microbiological hazards presently receive the most attention, there are several appeals for inclusion of pesticides,

allergens and natural toxins in risk assessments. Databases on these are provided/developing through the National Residue Survey and AusToxNet, respectively.

Another advantage of utilising industry data would be to offset some of the high cost of conducting risk assessments. Use of industry data would potentially offset a major expense and contribute a substantial in-kind contribution to project funding. This would, in-turn, provide a cost-effective mechanism for industry to immediately contribute (in-kind) to the conduct of targeted risk assessment research. This would provide a mechanism for industry to become considerable co-investors in projects, a requirement of most research funding models.

Biological validation of quality systems

The types of data gaps and epidemiological and statistical limitations of previous food borne hazard studies in animal populations are highlighted in the preslaughter management of livestock to minimise food safety hazards. The potential application of preslaughter reduction of food borne hazards was reinforced in a Quantitative Risk Assessment (QRA) of ground beef patties in which a reduction of consumer risk by 46% was predicted if the preslaughter level of contamination was controlled (Cassin *et al*, 1998). Opportunities for control have focused on the immediate preslaughter period. The impact of a 24-hour feed withdrawal prior to slaughter on the level of contamination is equivocal in sheep and cattle, varying from no change (Harmon *et al*, 1999, Kudva *et al*, 1997) to increased levels in sheep (Kudva *et al*, 1995).

In view of this information it is unclear whether the "feed curfew" procedure in FlockCare reduces the level of contamination (through less ingesta spillage, cleaner fleeces and cleaner transport) or leads to poorer hygiene through increased levels of *E. coli* and *Salmonella* spp. present in ingesta as a source of carcase contamination. In NZ lambs it has been demonstrated that the presence of faecal material or wool on the carcase was not associated with increased bacterial numbers on visually clean areas of the carcase. The presence of visible contamination alone cannot be used as an indicator of hygienic status of the carcase as a whole (Biss and Hathaway, 1996).

Further studies have identified hazard loads to be diet related with barley-based diets having lower levels than corn (Buchko *et al*, 2000). Feeding changes also offer opportunities for reducing levels with a change of diet followed immediately by feed withdrawal leading to a clearance of *E. coli* (Kudva *et al*, 1995). Any food safety ("feed curfew") measure then needs to also take into account its impact on eating quality.

In relation to the sensitivity of sample amounts, the faecal sample weight has been demonstrated to markedly influence estimates of prevalence in epidemiological studies. Until the advent of risk assessment there has not been such an emphasis on knowing the performance characteristics (ie. sensitivity) of the sampling methodology. Studies have placed emphasis on characterising isolates obtained from surveys, with much less attention being placed on the epidemiological representativeness and rigour of the published estimates of prevalence. The relative sensitivity of samples of pig faeces for the recovery of *Salmonella* spp. varied from 22% with 1gm, 52% with 10gm and 78% with 25 gm samples (Funk *et al*, 2000). A subsequent Australian study of the prevalence of *E. coli* O157:H7 in dairy cows at slaughter (Hallaran and Sumner, 2001) used 10gm samples of large intestinal ingesta that is likely to give greater sensitivity and data rigour. Standardisation of sample volume based on the known relative sensitivity, as well as knowing the sensitivity of the diagnostic test is, therefore, critical in increasing the utility of such prevalence data for QRA purposes from which control procedures capable of reducing risk can be reliably defined.

Important aspects in applying a risk-based approach to reducing the level of contamination of meat include;

- taking a quantitative approach to ultimately enable an estimate of risk reduction and attribute risk
- characterising pathways/opportunities for contamination in different production systems
- using methodologies (ie. reliable sample weights and determining levels of contamination as well as presence/absence) that will enable data to be interpreted in a QRA process modelling context.

Through-chain surveillance

Linking industry performance with public health outcomes has been consistently recommended. Both the National Safe Food System (1997) and the Blair Report (1998) recommended its integration. Public health surveillance data can be used to prioritise hazards for attention down the supply-chain and also provides evidence of the efficacy of risk management measures.

While there have been several reports recommending food borne disease surveillance for the livestock industries over several years, there is still a lack of risk-based surveillance. The grains industry is formulating its risk-based approach to on-farm quality assurance (SafeFood NSW, 2000). OzFoodNet is generating valuable information on the incidence and cause of public health food borne disease outbreaks (Kirk, 2001). At a minimum, those responsible for surveillance and food safety programs in the primary sector must utilise OzFoodNet data to prioritise primary industry programs based on consumer risk. This will require consultation between OzFoodNet and animal health epidemiologists to review food borne risk-based surveillance in the primary sector.

Conversely, with better hazard surveillance data from the primary and processing sectors, there is an opportunity to review public health surveillance priorities. Current food borne surveillance focuses on the common microbiological agents which cause gastrointestinal disease. However, there is a range of hazards (natural toxins) which may cause syndromes other than gastro-intestinal illness. Without monitoring potential outcomes from these hazards it is not possible with certainty to prioritise hazards in pre-slaughter and pre-harvest programs.

This results in Australia having a limited range of information on which to base effective risk prioritisation of programs, analyse needs or verification of the public health impact of the programs implemented. From an export control point of view, this is not of direct importance as the measure of our success lies in the frequency and extent of disruptions to the export trade. However, domestic problems have a significant impact on exports, as importing authorities usually require assurances whenever they become aware of significant domestic food safety issues. We must also be prepared, in the wake of high profile cases such as the outbreaks of BSE in the United Kingdom and continental Europe, for overseas authorities to become more demanding in requiring food safety claims to be backed by quantitative data.

A recent review of Australia's animal disease surveillance systems, "Animal Disease Surveillance Program: Baseline Study" (AusVet, 2001), commissioned by Animal Health Australia and the National Veterinary Committee has been conducted. One of the major conclusions is there is no process for risk-based prioritisation of investment in surveillance programs. As a large proportion of food borne pathogens exist asymptomatically in animal populations, and production and marketing practices may increase levels, it is important a through-chain perspective is included in the "risk-based" prioritisation process. Resources to facilitate this shift in emphasis are not apparent. In a recent review of the Veterinary Laboratory Service in the UK in relation to meeting its veterinary public health charter, Hathaway (pers com) found that this was largely comprised of diagnosis of clinical disease due to Salmonellosis (ie animals unlikely to be entering the food-chain for some time) and as such failed to address food borne hazards circulating in clinically normal populations that enter the food-chain.

A project to implement pro-active, risk-based surveillance across the supply-chain is required. This will enhance the value of non-human microbiological databases, (ie National Enteric Pathogen Surveillance Scheme). Specifically, integrating information from OzFoodNet (incidence attack rates, sources of contamination, risk factors for food borne disease) with levels of contamination of hazards along the food supply-chain is essential for comprehensive risk assessments. Regulators specified this feature will differentiate any new initiatives from the current situation. Better food borne disease surveillance information is also recognised as being a powerful tool to identify gaps in required knowledge and to prioritise research accordingly as well as validating risk estimates from risk assessments.

The value of non-human microbiological databases was, however, ranked of "low to medium" importance by stakeholders. The lack of systematic monitoring by industry and inconsistent reporting (ie notifiable) between states, makes interpretation of this data difficult. However stakeholders

recognised the value of this type of information to detect longer-term shifts in pathogen levels which may assist in focusing investigations of food borne outbreaks.

CONCLUSIONS

Australian food industry stakeholders strongly endorse the need to undertake risk assessments that involve the entire food supply-chain. These require coordination of resources and programs across sectors of the product supply-chain. This process will enable selection of practical food safety procedures that effectively and efficiently provide the acceptable level of consumer protection. The development of a Quantitative Risk Assessment (QRA) model for a hazard/product pair provides industry with:

- a tool to predict how changes in industry practices impact on the occurrence of the risk in humans so delivering an authoritative method for optimising the benefits from HACCP.
- a tool to define (Critical) Control Points and Critical Limits through-chain as production systems change and processing technologies evolve
- a tool to assist harmonisation of Quality Assurance systems nationally
- a risk-based tool for prioritising food safety R&D
- a model to evaluate the food safety risk of alternative control measures and production systems
- capacity to design production systems to minimise risk, and
- a risk-based tool for reviewing microbiological monitoring standards for the product.

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